UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA,	***)***	
	)	
Plaintiff	***)***	
	)	
v.	***)***	***Docket No. 05-163-P-H***
	)	
CAP QUALITY CARE, INC.,	***)***	
	)	
Defendant	***)***	

MEMORANDUM DECISION ON MOTION TO EXCLUDE AND RECOMMENDED DECISION ON MOTIONS FOR PARTIAL SUMMARY JUDGMENT

In this case involving claims of Medicaid fraud and violations of the False Claims Act and the Comprehensive Drug Abuse Prevention and Control Act by a methadone clinic located in Westbrook, Maine, both parties have filed motions for summary judgment which address Count 4 of the Second Amended Complaint. The defendant's motion also involves several other counts. The defendant has also filed a motion to exclude certain expert testimony proffered by the plaintiff. I deny the motion to exclude and recommend that the court deny the plaintiff's motion for partial summary judgment and grant the defendant's motion in part.

I. Motion to Exclude

The defendant seeks to exclude all or part of the testimony of Michael LaCombe, M.D. and Nicholas Reuter, M.P.H. Motion to Exclude Certain Testimony by Plaintiff's Experts ("Motion to Exclude") (Docket No. 133) at 2-4. It "objects to any testimony by Dr. Lacombe about the back-dating of documents or about whether Dr. [Shinderman] practiced medicine in Maine without a license." *Id*. at 3.

The defendant offers the following reasons why Dr. LaCombe should not be allowed to testify about the backdating of documents:

> It is unclear what, if any, scientific, technical or specialized knowledge that Dr. Lacombe has to offer an opinion that a document is backdated. Dr. Lacombe's report, which accompanied the Plaintiff's expert designation, simply offers the conclusion and nothing more that certain treatment plans have been backdated.

Id. This is an apparent reference to the requirements that expert testimony be reliable and that an expert witness be qualified to express the opinion to be elicited. Fed. R. Evid. 702.

The plaintiff states that Dr. LaCombe will express the opinion that the defendant backdated certain records, "which is contrary to the applicable standards for medical record-keeping." Opposition to Defendant's Motion to Exclude Certain Expert Testimony ("Expert Opposition") (Docket No. 138) at 1. In the expert witness designation served by the plaintiff, Dr. LaCombe's report is incorporated by reference. Dr. LaCombe Expert Designation ("LaCombe Designation") (Attachment 4 to Expert Opposition) at 2. The defendant's characterization of LaCombe's report — as distinct from the plaintiff's designation — is incomplete. The report is admittedly brief, but it does offer more than a mere conclusion, referring the reader to specific pages in the patient records which "suggest[]" backdating. LaCombe's Expert Opinion (Attachment 2 to Expert Opposition) ¶ 13. It may well be that Dr. LaCombe believes that the backdating is obvious and needs no further explanation; if so, expert opinion on that point would not be necessary. However, to assert that backdating is "contrary to the applicable standards for medial record-keeping," LaCombe Designation ¶ 2(a), does require expert testimony.

In a declaration attached to the plaintiff's opposition to the motion, Dr. LaCombe states that he served from 1991 to 2000 on two national standards-setting organizations, the American Board of Internal Medicine and the American College of Physicians Board of Regents, which organizations, working together

with the several American Boards of Medical Specialties, set standards for medical practice and care, including standards for the maintenance of medical records. Declaration of Dr. Michael LaCombe ("LaCombe Decl.") (Attachment 1 to Expert Opposition) ¶ 7. Dr. LaCombe "participated in the process of setting those standards." *Id*. He also has experience as a practicing physician in Maine. *Id*. ¶ 8. This is sufficient to qualify Dr. LaCombe to testify about medical record-keeping standards and practices and to make his testimony reliable. The defendant offers no suggestion that such standards vary with the specialty practiced by a particular physician.

With respect to Dr. LaCombe's anticipated opinion that Dr. Shinderman practiced medicine in Maine without a license, the defendant asserts that the question "whether Dr. Shinderman was licensed to practice medicine in Maine after a certain date" is "a legal [question] to which it is doubtful that Dr. Lacombe offers any specialized knowledge." Motion at 3. So phrased, the question may well be a legal one. The opinion Dr. LaCombe will offer, however, is not whether Dr. Shinderman's license to practice medicine in Maine expired on August 9, 2002, but rather whether Dr. Shinderman practiced medicine in Maine after that date. LaCombe Designation at 2; LaCombe Decl. ¶ 8. Like all expert witnesses, Dr. LaCombe in his testimony assumes certain facts as they have been presented to him by the party offering his testimony. In this case, his testimony assumes that Dr. Shinderman's license to practice medicine in Maine expired on August 9, 2002. The fact that the parties may differ as to the date on which Dr. Shinderman's license to practice medicine in Maine expired, if at all, does not render Dr. LaCombe's testimony inadmissible. Dr. LaCombe is qualified to testify about whether Dr. Shinderman's activities after August 9, 2002 constituted the practice of medicine rather than consulting.

In its reply memorandum, the defendant asserts that the plaintiff in its opposition "attempts to redefine the particulars of its experts' expected testimony and the qualification of those experts to give the

proffered testimony." Def[e]ndant's Reply to Plaintiff's Opposition to Motion to Exclude Certain Testimony, etc. ("Expert Reply") (Docket No. 152) at 1. It offers no specific discussion or citation to any document to support its contention that the plaintiff has "redefined" Dr. LaCombe's qualifications and none is apparent in the record made available to the court. With respect to his expected testimony, the defendant states that "Plaintiff now indicates that Dr. Lacombe will opine on the differences between practicing medicine and consulting on medical issues . . . ." *Id*. This is nothing new. In its expert designation, the plaintiff stated, *inter alia*: "[I]t is Dr. LaCombe's expert opinion that Dr. Shinderman practiced medicine in Maine after his license expired on August 9, 2002. . . . Moreover, CAP's records reflect that Dr. Shinderman's conduct was more consistent with the role of an attending physician at the clinic, as opposed to a 'consultant.'" LaCombe Designation at 2. The defendant goes on to assert that "Plaintiff does not provide any convincing evidence that its expert, a cardiologist by training, is qualified to testify about such an issue as it relates to the practice of addiction medicine by a psychiatrist in a methadone clinic." Reply at 1-2. There is no need for the plaintiff to provide any such evidence, let alone "convincing" evidence, in the absence of any authority for the proposition that the distinction between practicing medicine and medical consulting differs from medical specialty to medical specialty. Dr. LaCombe's opinion is expressed in general terms. On the showing made, that is sufficient.[1]

With respect to Reuter, the defendant asserts that

> [i]t is not clear from either Plaintiff's expert designation or from Mr. Reuter's report whether he intends to offer an opinion about whether a particular patient medically or clinically needed a so-called split-dose of methadone. It does not appear from Mr. Reuter's recitation of his background and experience in his report that he is qualified to offer an opinion about whether an OTP patient

[1] The defendant asserts that "it is also questionable whether such testimony would actually assist the trier of fact to understand the evidence." Expert Reply at 2. In the absence of developed argument, the court will not consider this tentative yet conclusory assertion.

> medically needs a split-dose of methadone. . . . In a similar vein, it appears that Mr. Reuter might try to offer an opinion as to whether a particular OTP patient received adequate substance abuse counseling as clinically necessary; whether a patient received an adequate level of counseling in the early stabilization phase of treatment; and whether a patient's treatment plan was individualized. There is no indication in the Plaintiff's expert designation of Mr. Reuter or in Mr. Reuter's recitation in his report of his background and experience that indicates that he is qualified to offer an opinion on such matters.

Motion at 4. The plaintiff responds that Reuter will testify on the question whether the defendant's records include the necessary documentation and approvals for allowing the patient to take methadone home, not whether a particular patient medically or clinically needed a split-dose of methadone. Expert Opposition at 5. This distinction is critical and is ignored by the defendant. In its reply, the defendant asserts that "the Plaintiff continues to insist that this expert is qualified to assess whether a methadone patient is clinically a candidate for split-dose methadone," citing as an example "testimony that [the plaintiff] expects to elicit from Reuter" the statement "I can find no record . . . that would help confirm that the patient is a fast metabolizer and clinically a candidate for split dosing." Expert Reply at 2. That statement is not in any sense an expression of an opinion that the patient at issue was or was not "clinically a candidate for split dosing." It is a statement that the required records that would document that the patient at issue was clinically a candidate for split dosing are not present at the defendant's facility. When the testimony is properly characterized, Reuter's extensive qualifications to give it are apparent. Expert Opposition at 4-5; Second Declaration of Nicholas Reuter (Attachment 6 to Expert Opposition) ¶¶ 4-6.

With respect to Reuter's anticipated testimony about the counseling of and treatment plans for particular patients, the defendant appears to challenge only his qualifications so to testify. The qualifications cited immediately above are sufficient to allow Reuter to give this testimony as well. In its reply, the defendant asserts that "Plaintiff's response also raises the issue of whether Mr. Reuter's expected testimony

inappropriately renders opinions which are matters of law for the Court. . . . To the extent Mr. Reuter's testimony is intended to describe the plaintiff's interpretation of the regulations, it is improper." Expert Reply at 2. The defendant does not identify the language in the plaintiff's opposition that raises this specter, and I see nothing to justify the defendant's asserted fear. Should counsel for the plaintiff ask inappropriate questions of Reuter at trial, the usual procedure of asserting an objection before an answer is given should suffice.

The motion to exclude is denied.

II. Motions for Partial Summary Judgment

A. Summary Judgment Standard

1. Federal Rule of Civil Procedure 56. Summary judgment is appropriate only if the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Santoni v. Potter*, 369 F.3d 594, 598 (1st Cir. 2004). "In this regard, 'material' means that a contested fact has the potential to change the outcome of the suit under the governing law if the dispute over it is resolved favorably to the nonmovant. By like token, 'genuine' means that 'the evidence about the fact is such that a reasonable jury could resolve the point in favor of the nonmoving party.'" *Navarro v. Pfizer Corp.*, 261 F.3d 90, 93-94 (1st Cir. 2001) (quoting *McCarthy v. Northwest Airlines, Inc.*, 56 F.3d 313, 315 (1st Cir. 1995)).

The party moving for summary judgment must demonstrate an absence of evidence to support the nonmoving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). In determining whether this burden is met, the court must view the record in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences in its favor. *Santoni*, 369 F.3d at 598. Once the moving party has made a preliminary showing that no genuine issue of material fact exists, the nonmovant

must "produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue." *Triangle Trading Co. v. Robroy Indus., Inc.*, 200 F.3d 1, 2 (1st Cir. 1999) (citation and internal punctuation omitted); Fed. R. Civ. P. 56(e). "As to any essential factual element of its claim on which the nonmovant would bear the burden of proof at trial, its failure to come forward with sufficient evidence to generate a trialworthy issue warrants summary judgment to the moving party." *In re Spigel*, 260 F.3d 27, 31 (1st Cir. 2001) (citation and internal punctuation omitted).

As to Count 4 of the Second Amended Complaint, the parties have filed cross-motions for summary judgment. "This framework is not altered by the presence of cross-motions for summary judgment." *Cochran v. Quest Software, Inc*., 328 F.3d 1, 6 (1st Cir. 2003). "[T]he court must mull each motion separately, drawing inferences against each movant in turn." *Id*. (citation omitted); *see also, e.g., Wightman v. Springfield Terminal Ry. Co*., 100 F.3d 228, 230 (1st Cir. 1996) ("Cross motions for summary judgment neither alter the basic Rule 56 standard, nor warrant the grant of summary judgment *per se*. Cross motions simply require us to determine whether either of the parties deserves judgment as a matter of law on facts that are not disputed. As always, we resolve all factual disputes and any competing, rational inferences in the light most favorable to the [nonmovant].") (citations omitted).

2. Local Rule 56. The evidence the court may consider in deciding whether genuine issues of material fact exist for purposes of summary judgment is circumscribed by the Local Rules of this District. *See* Loc. R. 56. The moving party must first file a statement of material facts that it claims are not in dispute. *See* Loc. R. 56(b). Each fact must be set forth in a numbered paragraph and supported by a specific record citation. *See id*. The nonmoving party must then submit a responsive "separate, short, and concise" statement of material facts in which it must "admit, deny or qualify the facts by reference to each numbered paragraph of the moving party's statement of material facts[.]" Loc. R. 56(c). The nonmovant likewise must support

each denial or qualification with an appropriate record citation. *See id*. The nonmoving party may also submit its own additional statement of material facts that it contends are not in dispute, each supported by a specific record citation. *See id*. The movant then must respond to the nonmoving party's statement of additional facts, if any, by way of a reply statement of material facts in which it must "admit, deny or qualify such additional facts by reference to the numbered paragraphs" of the nonmovant's statement. *See* Loc. R. 56(d). Again, each denial or qualification must be supported by an appropriate record citation. *See id*.

Failure to comply with Local Rule 56 can result in serious consequences. "Facts contained in a supporting or opposing statement of material facts, if supported by record citations as required by this rule, shall be deemed admitted unless properly controverted." Loc. R. 56(e). In addition, "[t]he court may disregard any statement of fact not supported by a specific citation to record material properly considered on summary judgment" and has "no independent duty to search or consider any part of the record not specifically referenced in the parties' separate statement of fact." *Id*.; *see also, e.g.*, *Cosme-Rosado v. Serrano-Rodriguez*, 360 F.3d 42, 45 (1st Cir. 2004) ("We have consistently upheld the enforcement of [Puerto Rico's similar local] rule, noting repeatedly that parties ignore it at their peril and that failure to present a statement of disputed facts, embroidered with specific citations to the record, justifies the court's deeming the facts presented in the movant's statement of undisputed facts admitted." (Citations and internal punctuation omitted).

B. Factual Background

The parties' statements of material facts include the following undisputed material facts.

1. As to Count 4 ("Medicaid Fraud And Recoupment — Distributing Methadone in Violation of 42 [C.F.R.]. § 8.12(i)").

One objective of methadone maintenance treatment is for the patient to reach a "comfort zone" in which the serum methadone levels remain within a therapeutic range from one dosing to the next. CAP Quality Care's Additional Material Facts ("CAP Additional SMF") (Docket No. 144) ¶ 6; Government's Reply to CAP's Additional Statement of Fact ("Plaintiff's Additional Responsive SMF") (Docket No. 151) ¶ 6. The dose of methadone required for a patient to reach and stay in the therapeutic range will differ from patient to patient. *Id*. If the serum methadone level is within the therapeutic range, the patient will not show signs of either over- or under-medication. *Id*. Most methadone patients require only one daily dose of methadone, but for some patients, a single daily dose is not efficacious. *Id*. ¶ 7. This problem stems from a rapid decline in serum methadone levels during the dosing interval in those individuals who are rapid metabolizers of methadone. *Id*. Attempts to block the onset of withdrawal that occurs before the next dose most often involves raising the dose of methadone. *Id*. As a result, patients who are rapid metabolizers can be subjected to both over- and under-medication from one dosing interval to the next. *Id*.

Rapid metabolism of methadone results in the patient experiencing withdrawal symptoms before receiving the next dose of methadone. *Id*. ¶ 8. Increasing the daily dose of methadone will only result in over-medication early in the dosing cycle while withdrawal symptoms will still occur later in the cycle. *Id*. Research has demonstrated that this problem can be solved by shortening the methadone dosing interval and providing methadone twice a day rather than once a day, which is known as "split-dosing." *Id*. ¶ 9. This does not require an increase in the daily dose of methadone and is an accepted treatment practice in methadone maintenance programs. *Id*. A split-dose results in a more consistent blood level of methadone and the patient remains in the therapeutic range throughout the day. *Id*. Split-dosing allows a patient to

stabilize and become more functional, which increases the chances that the patient will remain in treatment. *Id*. ¶ 10. For some patients, traveling to the clinic more than once a day for their methadone may cause the patients to drop out of treatment. *Id*. Under CAP's split-dosing regimen, patients had on-going daily contact with the clinic and would be observed for at least one dosing administration. *Id*. ¶ 22. By January 2003 new patients at CAP were no longer granted split-dosing privileges and only a comparatively small number of previously admitted patients were permitted to have split-dosing privileges. *Id*. ¶ 27.

CAP initially submitted "exception" applications to state regulatory officials in late 2001 for some or all split-dose patients. *Id*. ¶ 39.

Between September 11, 2001 and January 3, 2003 the defendant had a policy entitled "Split Dosages and Patient Doses [that] Exceed 100 mg," which provided, in part: "If a patient exhibits sedation after two to four hours, however reports withdrawal symptoms later in the day, a split dose would be recommended. The patient would be required to attend the clinic twice daily until the counselor submits the required paperwork to our state and federal regulatory agencies (the patient must have one illicit drug free urine before we submit the paperwork)." *Amended* Statement of Undisputed Material Facts in Support of Plaintiff's Motion for Partial Summary Judgment ("Plaintiff's SMF") (emphasis in original) (Docket No. 136) ¶ 1; CAP Quality Care's Responses to the Plaintiff's Statement of Material Facts ("CAP Responsive SMF") (Docket No. 141) ¶ 1. [2] When the defendant provided a patient with "split dose" methadone, it

[2] The defendant's qualification response to paragraph 1 of the plaintiff's statement of material facts admits that it produced the document from which this statement is taken in response to a subpoena issued by the inspector general of the Department of Health and Human Services but "denies that the document was incorporated and made a part of CAP Quality Care, Inc.'s official Standard Operating Procedure manual during the time frame of 2001 through 2003," citing paragraph 6 of the affidavit of Noa Shinderman. CAP Responsive SMF ¶ 1. That carefully-worded paragraph of the affidavit does not support the statement in the responsive statement of material facts for which it is cited as authority. Indeed, what Noa Shinderman, president of the defendant, states is that "[a]fter a search of CAP's records, I could find no record that the policy reflected in this document was implemented by CAP. In addition, I have no recollection of its implementation." Affidavit of Noa Shinderman (Attachment 5 to CAP Additional SMF) ("N. Shinderman Aff.") ¶¶ 1, 6.

almost always allowed the patient to ingest the second portion of the daily methadone dose away from the clinic; unless a CAP physician expressly ordered an "observed split dose," CAP's patients did not return to the clinic for observation of their intake of the second portion of their daily methadone dose. *Id.* ¶ 2. When the defendant provided a patient with "split dose" methadone, it provided that patient two doses of methadone each day. *Id.* ¶ 3.

The federal opioid treatment regulations set forth under 42 C.F.R. Part 8 include discussion of the dispensing of opioid treatment medications, essentially methadone, to opioid dependent individuals. *Id.* ¶ 4.[3] The regulations impose restrictions on how methadone is provided to patients for ingestion away from the clinic, reflecting concerns that individuals dependent on or addicted to illicit opiates like heroin, or illicit opioids, such as oxycodone, pose risks to the public and themselves when provided with a substance like methadone, which has the potential for abuse and diversion. *Id.* ¶¶ 5-6. The regulations include a schedule for dispensing methadone that is tied to the patient's time-in-treatment, as well as a program's physician's judgment on the patient's stability, rehabilitative progress, criminal activity, home environment and other factors. *Id.* ¶ 8. A methadone clinic physician must determine each eligible patient's suitability for take-home methadone in accordance with an 8-point list of criteria. *Id.* ¶ 10.[4] An exemption provision is found

[3] Beginning with this paragraph of the plaintiff's statement of material facts, the defendant states the following objection to 9 of the paragraphs in this statement of material facts and again to 15 paragraphs in the statement of additional facts submitted by the plaintiff in opposition to the defendant's motion for partial summary judgment: "Pursuant to Local Rule 56(e) this paragraph should be stricken because it involves multiple statements in one paragraph and Local Rule 56(b) requires that each material fact be set forth in a separately numbered paragraph." Plaintiff's Responsive SMF ¶¶ 4-5, 8, 10-14, 16; CAP Quality Care's Reply to the Government's Additional Facts in Response to CAP Quality Care's Motion for Partial Summary Judgment ("CAP Additional Responsive SMF") (Docket No. 153) ¶¶ 79, 100-01, 104-05, 107-16. First, this is an incorrect characterization of Paragraph 4 of the plaintiff's statement of material facts. Even if it were correct, the terms of Local Rule 56(b) do not mean that each paragraph may contain only one sentence. *Randall v. Potter*, 366 F.Supp.2d 120, 122 (D. Me. 2005). None of the paragraphs which the defendant asserts should be stricken consists of more than 11 typed lines; some have only 3 typed lines. If there is a violation of Local Rule 56(b) in any of these paragraphs, it is not of sufficient magnitude to support the sanction sought by the defendant. All of these requests to strike are denied.

[4] In addition to the multiple-statement objection which I have already overruled, the defendant also objects to this (*continued on next page*)

at 42 C.F.R. § 8.11(h) to address situations where a patient may be unable to report to the methadone clinic for dosing. *Id*. ¶ 11.[5]

Most exemption requests submitted under 42 C.F.R. § 8.11(h) involve a patient who needs additional take-home supplies of methadone beyond what is permitted by the time-in-treatment requirements. *Id*. ¶ 12.[6] In such cases, a physician considers the 8-point criteria in determining each patient's suitability for the amount to be dispensed. *Id*. The methadone clinic then conveys these findings to the federal regulators together with other information about each patient, admission date, dose level, nature of request and the justification for the requested exemption. *Id*. Of the approximately 30,000 requests for patient exemptions received and reviewed by the federal regulators each year, approximately 2-3 per day are for split-dose take-home methadone. *Id*. ¶ 15.[7]

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paragraph of the plaintiff's statement of material facts as follows: "Pursuant to Local Rule 56(e) this paragraph should be stricken because it contains a legal conclusion in that it interprets regulations and applies it [sic] to a set of facts which is not appropriate for a Statement of Material Facts." Defendant's Responsive SMF ¶ 10. Local Rule 56(e) does not deal with the permissible content of a statement of material facts; it merely sets out the procedure for requests to strike material from such statements. The paragraph does not present a legal conclusion; the statements stricken in *Rockwell Burr Sign & Design, Inc. v. Gulf Ins. Co*., 2003 WL 22063550 (D. Me. 2003), at *1, the other authority cited by the defendant, Defendant's Responsive SMF ¶ 10, are not repeated in that decision, which accordingly can stand only for the general principle that legal conclusions may be stricken from a statement of material facts. Here, the paragraph at issue cites as authority the report of an expert witness. Plaintiff's SMF ¶ 10. To the extent that the cited portion of that witness's report is a restatement of 42 C.F.R. § 8.12(i), Expert Testimony — Nicholas Reuter, M.P.H. (attached to Declaration of Nicholas Reuter (Attachment 37 to Plaintiff's SMF)) ¶ 8, it is an accurate restatement. The objection is overruled. Finally, the defendant states that "[t]o the extent a response is required, it is **DENIED**. See Rockwell Burr, supra." Plaintiff's Responsive SMF ¶ 10. That case law does not provide any basis for demonstrating a dispute about any facts included in paragraph 10 of the defendant's statement of material facts. The paragraph is accordingly deemed admitted.

[5] The defendant makes the multiple-statement and legal-conclusion objections to this paragraph of the plaintiff's statement of material facts. Defendant's Responsive SMF ¶ 11. They are overruled for the reasons set forth in footnote 4 above. The defendant agrees that the regulation provides an exemption; it disputes the plaintiff's characterization of the entity to which the exemption applies. *Id*. I do not rely on that characterization and have not included it in my factual recitation.

[6] The multiple-statement and legal-conclusion objections made to this paragraph by the defendant, Defendant's Responsive SMF ¶ 12, are overruled.

[7] The defendant's objection to this paragraph of the plaintiff's statement of material facts on the ground that it is irrelevant, Defendant's Responsive SMF ¶ 15, is overruled.

(a) Patient M602

On March 28, 2002 patient M602 began receiving treatment at CAP. *Id*. ¶ 17. At that time CAP knew that (i) M602 had tested positive for methadone; (ii) M602 was using illicit methadone, heroin and Oxycontin prior to beginning treatment at CAP; (iii) M602 had, within the previous year, been arrested once for substance abuse; (iv) M602 was living with her father or friends depending on whether she had money or not; and, for M602, the issue of suitable housing was identified by CAP as a problem and/or need. *Id*. ¶ 18. On April 10, 2002 M602 told her CAP counselor and a CAP doctor that she "still uses." *Id*. ¶ 19. On April 25, 2002 M602 informed CAP that she was 'still using." *Id*. ¶ 20. On about April 29, 2003 M602 reported to CAP that she had used illegal Klonopin. *Id*. ¶ 21. In May 2002 CAP knew that M602 was continuing to abuse illicit and prescription drugs, including illicit benzodiazepines. *Id*. ¶ 22. On May 2, 2002 M602 stated she took two illicit Xanex the evening before. *Id.* ¶ 23. On May 3, 2002 M602 threatened suicide. *Id*. ¶ 24. On May 4, 2002 a CAP physician note reflects that M602 presented intoxicated and had taken illicit Klonopin. *Id*. ¶ 25.

On May 22, 2002 M602 requested take-home medications, but she was told by her counselor that CAP was "unable to do this." *Id*. ¶ 26. In May 2002 CAP administered non-methadone prescription drugs to M602 at the clinic's nursing window. *Id.* ¶ 27. On June 10, 2003 M602 reported to CAP that she was abusing the drug Trazadone. *Id*. ¶ 28. On or about June 14, 2002 there were specific discussions among CAP's management regarding the risk of providing take-home methadone to M602 which included e-mails among Marc Shinderman, CAP's National Medical Director, Steve Cotreau, CAP's Clinic Director, and Dr. Keefe. *Id*. ¶ 29. On July 2, 2002 CAP began providing M602 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week

when the clinic was open. *Id.* ¶ 30.[8] CAP did not obtain an exemption for M602. *Id.* ¶ 31.[9] On July 2, 3, 5, 6 and 8 M602 did not return to CAP to take the second portion of her daily methadone. *Id.* ¶ 32.[10] On July 9, 2002 M602 informed CAP that she had diverted her methadone which resulted in a death. *Id.* ¶ 33.

(b) Patient M409

On January 7, 2002 patient M409 began treatment at CAP. *Id.* ¶ 34. On that date, M409 reported her current use of opiates to be 20 bags of heroin and 25 mg per day of Oxycontin. *Id.* ¶ 35. M409 also reported that she had been using drugs (anywhere from 10 bags of heroin per day to 40 bags of heroin in the two days preceding her intake) for two and one-half weeks; had previously received six months of treatment at Discovery House; and had been in prison for three months and was released 18 days before beginning treatment at CAP. *Id.* On January 7, 2002 M409 tested positive for drugs. *Id.* ¶ 36. On January 12, 2002 M409 was clearly intoxicated when she was at CAP. *Id.* ¶ 37. On January 16, 2002 CAP began providing M409 with split-dose take-home methadone such that the patient took methadone

[8] The defendant purports to deny this paragraph of the plaintiff's statement of material facts, Defendant's Responsive SMF ¶ 30, but its denial is not responsive to the substance of the paragraph. The same non-responsive denial is made to every paragraph of the plaintiff's statement of material facts that records a particular patient taking methadone home from CAP. I will not repeat the objection every time; it is overruled each time it appears. The defendant also responds with a qualification to the effect that M602 was entitled to holiday and Sunday take home doses and that July 4, 2002 was a holiday and July 7, 2002 was a Sunday. *Id.*

[9] Every time this statement is made about a particular patient, the defendant provides the same qualifying response: it maintains that a split does did not require an application for an exemption. *E.g.*, Defendant's Responsive SMF ¶ 31. I will not mention this qualification every time I state this fact about a particular patient.

[10] The defendant purports to deny this paragraph of the plaintiff's statement of material facts, asserting that "the citation does not stand for the proposition cited with respect to CAP Dep. [a]t 81-82 because the Deponent was equivocal in those answers and does not meet the requirements of competency set forth in F.R.E. 602," Defendant's Responsive SMF ¶ 32(a), a rather curious objection since the deponent at issue was the defendant's corporate designee under Fed. R. Civ. P. 30(b)(6), Plaintiff's SMF at 2 n.2, but I have reworded the paragraph to follow more closely the other cited source, *see* Declaration of Eric Hafener ("Hafener Decl.") (Attachment 1 to Docket No. 129) ¶ 10(m). The defendant objects to this source as well, stating that "Hafener's Declaration ¶ 10 is unsupported by the record because although the physician orders reflect a split dose, other records including the individual dosing history are neutral, see Bates No. F-09131." Defendant's Responsive SMF ¶32(b). There is no suggestion in that paragraph or elsewhere in the defendant's responsive statement of material facts as to where "Bates No. F-09131" might be found. I found it as the twenty-fifth page of Attachment 4 to Docket No. 129, an attachment entitled "Patient 602," but without further informed interpretation, I am unable to read Bates No. F-09131 to be "neutral" or other than neutral on the relevant point. I have accordingly deemed

(*continued on next page*)

away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 38.[11] On January 24, 2002 a CAP counselor wrote that M409 used street methadone "4 days ago" and was not stable; nevertheless, CAP continued to provide M409 with split-dose take-home methadone. *Id*. ¶ 39. CAP did not obtain an exemption for M409. *Id*. ¶ 40. On February 27, 2002 CAP stopped providing M409 with split-dose take-home methadone when M409 disclosed that her boyfriend died after taking her split dose. *Id*. ¶ 42.[12]

(c) Patient M538

On February 28, 2002 patient M538 began treatment at CAP. *Id*. ¶ 43. On February 28, 2002 M538 tested positive for methadone and opiates. *Id*. ¶ 44(a). Despite having entered methadone treatment one week earlier at a different methadone clinic, M538 was continuing to use illicit heroin, at least 10 bags per day. *Id*. ¶ 44(b). M538 had drug charges pending. *Id*. ¶ 44(c). On March 6, 2002 CAP began to provide M538 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 45.[13] On March 13, 2002 M538 tested negative for opiates. *Id*. ¶ 46. A CAP counselor progress note dated March 16, 2002 states that M538 "reports being unstable on current dose of split dose of 80-60 mg. Reports using 10 bags of heroin on 3/15/02." *Id*. ¶ 47. Despite knowledge of the foregoing, CAP continued to provide M538 with split-

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paragraph 10(m) of Hafener's declaration to be admitted.

[11] The defendant qualifies its response, despite admitting that the patient received a split dose on January 16, 2002, by stating that it "maintains that the patient was entitled to holiday and Sunday take[-]home doses .... January 20, 2002 was a Sunday and January 21, 2002 was the Martin Luther King Day holiday." Defendant's Responsive SMF ¶ 38b. The defendant goes on to challenge one of the sources cited by the plaintiff, the corporate deposition of the defendant, for the reasons stated in n.10 above. It does not challenge the citation to paragraph 11(c) of the Hafener declaration, which supports the paragraph as stated. Hafener Decl. ¶ 11(c).

[12] The defendant's purported denial of this paragraph of the plaintiff's statement of material facts is non-responsive, Defendant's Responsive SMF ¶ 42a, and it admits only part of the paragraph, *id*. ¶ 42b. Because the paragraph is fully supported by the citation given to the summary judgment record, the entire paragraph is deemed admitted.

[13] The defendant makes the same purported denials and limited admissions to this paragraph of the plaintiff's statement of (*continued on next page*)

dose take-home methadone through April 24, 2002, when she or he transferred to another facility. *Id*. ¶ 48. CAP did not obtain an exemption for M538. *Id*. ¶ 49.

(d) Patient M513

On February 19, 2002 patient M513 began treatment at CAP. *Id*. ¶ 51. CAP's intake documents reflect that M513 was using illicitly acquired methadone and pharmaceutical opiates at the time of intake. *Id*. ¶ 52. On February 21, 2002 CAP began providing M513 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week. *Id*. ¶ 53. M513's discharge summary states that M513 "secretly tapered herself off methadone by not taking her PM split, then drinking only half her AM split." *Id*. ¶ 54. CAP did not obtain an exemption for M513. *Id*. ¶ 55.

(e) Patient M421

On January 9, 2002 patient M421 began treatment at CAP. *Id*. ¶ 57. Based on information provided by M421 at intake, CAP was aware that M421 was using illicit methadone and Oxycontin and that M421 had overdosed the previous month when he used the "wrong drugs plus methadone." *Id*. ¶ 58. On January 12, 2002 CAP's records reflect that M421 "has been split dosing 60/60 (on his own)." *Id*. ¶ 59. On that date, CAP began providing M421 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 60. CAP did not obtain an exemption for M421. *Id*. ¶ 61.

(f) Patient M422

On January 9, 2002 patient M422 began treatment at CAP. *Id*. ¶ 63. On January 12, 2002 CAP began providing M422 with split-dose take-home methadone such that the patient took methadone away

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material facts as it makes to all similar paragraphs appearing before and after it. Defendant's Responsive SMF ¶ 45. I will
(*continued on next page*)

from the clinic more than three times per week when the clinic was open. *Id*. ¶ 65. Prior to April 5, 2002 CAP did not obtain an exemption for M422. *Id*. ¶ 66.

(g) Patient M540

On March 4, 2002 patient M540 began treatment at CAP. *Id*. ¶ 68. During the intake process, CAP learned that M540 was using Oxycontin and illicit methadone. *Id*. ¶ 69.[14] On March 7, 2002 CAP began providing M540 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 70. Prior to April 12, 2002 CAP did not obtain an exemption for M540. *Id*. ¶ 71. On October 28, 2002 a CAP physician's order states: "Pt incarcerated. Reports of unsecured doses by PO Dave Edwards with only Friday PM split and Sunday doses on his person. End split. 7 day take home doses status. New Dose = 200 mg. End Split." *Id*. ¶ 73.

(h) Patient M447

On January 17, 2002 patient M447 began treatment at CAP. *Id*. ¶ 74. During intake, M447 advised CAP that he was using 20-30 bags of heroin daily. *Id*. ¶ 75. On January 17, 2002 M447 tested positive for opiates; CAP did not test him again until March 21, 2002. *Id*. ¶ 76. On January 22, 2002 CAP began providing M447 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 77. CAP did not obtain an exemption for M447. *Id*. ¶ 78.

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no longer repeat my rulings on these identical denials, objections and partial admissions.

[14] The defendant's purported denial of this paragraph of the plaintiff's statement of material facts states: "The documents referenced in Hafener Declaration ¶ 16 [the cited source for the paragraph] are ambiguous as to the timeframe of the alleged Oxycontin, whether it was past or present abuse . . . ." Defendant's Responsive SMF ¶ 69. However, one of the underlying documents cited by Hafener, Hafener Decl. ¶ 16(a), does record under the heading "Current use of opiates" "oxy's and methadone/D," Attachment 10 to Docket No. 129 at F-08894.

(i) Patient M441

On January 15, 2002 patient M441 began treatment at CAP. *Id.* ¶ 80. On January 22, 2002 CAP began providing M441 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id.* ¶ 81. CAP did not obtain an exemption for M441. *Id.* ¶ 82.

(j) Patient M366

On December 17, 2001 patient M366 began treatment at CAP. *Id.* ¶ 84. During M366's intake, CAP learned that he was using Oxycontin and illicit methadone. *Id.* ¶ 85.[15] Also during intake, M366 tested positive for methadone. *Id.* ¶ 86.[16] On December 28, 2001 CAP began providing M366 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id.* ¶ 87. In March 2003 CAP suspended M366's split-dose take-home when it suspected that he was diverting his benzodiazepine prescription; M366 was required to attend the clinic twice a day. *Id.* ¶ 88. Prior to March 2003 CAP's medical director did not document in the patient record that the patient was stable for take-home doses by application of the 8-point criteria. *Id.* ¶ 89.[17] Prior to March 2003 CAP did not obtain an exemption for M366. *Id.* ¶ 90.

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[15] The defendant "denies that the documents referenced in Hafener Declaration ¶ 19(a) [the record evidence cited in support of the paragraph], specifically Bates No. F-06854 and Bates No. F-06873, substantiate the assertion that the patient was using heroin and Oxycontin at intake." Defendant's Responsive SMF ¶ 85. However, the first of those documents does state that the patient was using Oxycontin at the time of intake. Attachment 13 to Docket No. 129 at F-06854.

[16] The full text of this paragraph of the plaintiff's statement of material facts reads: "Also during intake, M366 tested positive for methadone despite not having been in methadone treatment prior to CAP (Hafener Declaration ¶ 19a)." Plaintiff's SMF ¶ 86. The defendant responded, in part: "CAP Quality Care, however, denies that document Bates No. F-06932 substantiates the assertion that the patient was not in treatment prior to CAP." Defendant's Responsive SMF ¶ 86(b). The defendant is correct. Attachment 13 to Docket No. 129 at F-06932. I note that this assertion is substantiated by F-06854, which is cited in support of the same paragraph in the Hafener declaration, but for a different factual proposition. Hafener Decl. ¶ 19(a). The court will not overlook this lapse in citation, which in any event is not determinative of any issue before the court in connection with the current motions for summary judgment.

[17] The defendant purports to deny this paragraph of the plaintiff's statement of material facts, but its "denial" is based on (*continued on next page*)

(k) Patient M274

On October 24, 2001 patient M274 began treatment at CAP. *Id*. ¶ 92. During intake, CAP learned that M274 was using illicit methadone, Oxycontin and cocaine. *Id*. ¶ 93. On October 30, 2001 a nursing note indicates that M274 used Tylox (a schedule II narcotic controlled substance) the night before, although it does not state whether the Tylox was from a valid prescription or illicit. *Id*. ¶ 94. On November 5, 2001 CAP began providing M274 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 95. On November 10, 2001 CAP's records reflect what appears to be the first urine screening for M274. *Id*. ¶ 96. On January 25, 2002 CAP documented concerns that M274 was suicidal. *Id*. ¶ 97. CAP continued to provide M274 with split-dose take-home methadone until July 26, 2005. *Id*. ¶ 98. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 99. CAP did not obtain an exemption for M274. *Id*. ¶ 100.

(l) Patient M402

On January 5, 2002 patient M402 began treatment at CAP. *Id*. ¶ 102. On January 19, 2002 CAP began providing M402 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 103. Prior to providing M402 with split-dose take-home methadone, CAP's medical director did not document in the

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an assertion that the 8-point criteria did not apply to administration of split-dosing. Defendant's Responsive SMF ¶ 89. This is not a denial of the stated fact but rather an argument concerning its legal significance. The defendant also states that the patient's record contained certain specific information, apparently intending to suggest that the criteria were met in substance. *Id*. Again, that is a legal argument. The paragraph is deemed admitted, as are others making the same assertion about other patients, to all of which the defendant makes the same denial.

patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 104. CAP did not obtain an exemption for M402. *Id*. ¶ 105.

(m) Patient M459

On January 23, 2002 patient M459 began treatment at CAP. *Id*. ¶ 107. On February 6, 2002 CAP began providing M459 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 108. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 109. CAP did not obtain an exemption for M459. *Id*. ¶ 110.

(n) Patient M539

On March 1, 2002 patient M539 began treatment at CAP. *Id*. ¶ 112. Prior to starting at CAP, M539 received four days of methadone treatment at another facility. *Id*. ¶ 113. On March 8, 2002 CAP began providing M539 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 114. Prior to providing M539 with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 115. CAP did not obtain an exemption for M539. *Id*. ¶ 116.

(o) Patient M294

On November 5, 2001 patient M294 began treatment at CAP. *Id*. ¶ 118. On November 20, 2001 CAP began providing M294 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 119. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in

the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 120. CAP did not obtain an exemption for M294. *Id*. ¶ 121.

(p) Patient M349

On December 10, 2001 patient M349 began treatment at CAP. *Id*. ¶ 123. On December 29, 2001 CAP began providing M349 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 124. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 125. CAP did not obtain an exemption for M349. *Id*. ¶ 126.

(q) Patient M74

On October 4, 2001 patient M74 began treatment at CAP. *Id*. ¶ 128. On November 2, 2001 CAP began providing M74 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 129. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 130. CAP did not obtain an exemption for M74. *Id*. ¶ 131.

(r) Patient M156

On October 22, 2001 patient M156 began treatment at CAP. *Id*. ¶ 133. On November 26, 2001 CAP began providing M156 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 134. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's

record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 135. CAP did not obtain an exemption for M156. *Id*. ¶ 136.

(s) Patient M340

On December 5, 2001 patient M340 began treatment at CAP. *Id*. ¶ 138. On January 11, 2002 CAP began providing M340 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 139. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 140. CAP did not obtain an exemption for M340. *Id*. ¶ 141.

(t) Patient M260

On December 14, 2001 patient M260 began treatment at CAP. *Id*. ¶ 143. On January 22, 2002 CAP began providing M260 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 144. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 145. CAP did not obtain an exemption for M260. *Id*. ¶ 146.

(u) Patient M309

On November 13, 2001 patient M309 began treatment at CAP. *Id*. ¶ 148. On December 31, 2001 CAP began providing M309 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 149. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in

the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 150. CAP did not obtain an exemption for M309. *Id*. ¶ 151.

(v) Patient M521

On February 21, 2002 patient M521 began treatment at CAP. *Id*. ¶ 153. On April 12, 2002 CAP began providing M521 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 154. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 155. CAP did not obtain an exemption for M521. *Id*. ¶ 156.

(w) Patient M105

On October 3, 2001 patient M105 began treatment at CAP. *Id*. ¶ 158. On November 28, 2001 CAP began providing M105 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 159. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 160. CAP did not obtain an exemption for M105. *Id*. ¶ 161.

(x) Patient M306

On November 12, 2001 patient M306 began treatment at CAP. *Id*. ¶ 163. On January 10, 2002 a CAP counselor wrote that M306 was involved in a domestic violence incident at home, after which she used Valium and alcohol to calm down. *Id*. ¶ 164. On January 11, 2002, CAP began providing M306 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 165. Prior to providing the patient with split-dose take-

home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 166. CAP did not obtain an exemption for M306. *Id*. ¶ 167.

(y) Patient M361

On December 14, 2001 patient M361 began treatment at CAP. *Id.* ¶ 169. On February 13, 2002 CAP began providing M361 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id.* ¶ 170. At that time, in the CAP Special Request/Doctor's Order requesting the split, a CAP employee wrote "Pt continues to have pain and buy 50g of methadone daily." *Id.* ¶ 171. M361's split-dose take-home doses continued until late August 2002. *Id.* ¶ 172. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id.* ¶ 173. CAP did not obtain an exemption for M361. *Id.* ¶ 174.

(z) Patient M302

On November 8, 2001 patient M302 began treatment at CAP. *Id.* ¶ 176. On January 23, 2002 CAP began providing M302 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id.* ¶ 177. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id.* ¶ 178. CAP did not obtain an exemption for M302. *Id.* ¶ 179.

(aa) Patient M131

On October 5, 2001 patient M131 began treatment at CAP. *Id.* ¶ 181. On December 22, 2001 CAP began providing M131 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id.* ¶ 182. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's

record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 183. CAP did not obtain an exemption for M131. *Id*. ¶ 184.

(bb) Patient M252

On October 20, 2001 patient M252 began treatment at CAP. *Id*. ¶ 186. On January 16, 2002 CAP began providing M252 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 187. CAP did not obtain an exemption for M252. *Id*. ¶ 188.

(cc) Patient M359

On December 14, 2001 patient M359 began treatment at CAP. *Id*. ¶ 190. On March 12, 2002 CAP began providing M359 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 191. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 192. CAP did not obtain an exemption for M359. *Id*. ¶ 193.

(dd) Patient M328

On November 29, 2001 patient M328 began treatment at CAP. *Id*. ¶ 195. On April 13, 2002 CAP began providing M328 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 196. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 197. CAP did not obtain an exemption for M328. *Id*. ¶ 198.

(ee) Patient M518

On February 20, 2002 patient M518 began treatment at CAP, having transferred from another methadone clinic after one year of treatment. *Id*. ¶ 200. On that date CAP's Patient File Data form indicated that M518 was living in a hotel. *Id*. ¶ 201. On February 21, 2002 CAP's Bio-Psycho-Social Assessment form for M518 indicated that M518 was on probation for drug charges. *Id*. ¶ 202. In February 2002 CAP's physician progress notes indicate that M518 admitted to using illicit Klonopin and that M518 tested positive for opiate drugs during intake. *Id*. ¶ 203. On February 25, 2002 CAP began providing M518 with split-dose take-home methadone such that the patient took methadone away from the clinic more than three days per week when the clinic was open. *Id*. ¶ 204. Prior to providing the patient with split-dose take-home methadone, CAP's medical director did not document in the patient's record that the patient was stable for take-home doses by application of the 8-point criteria. *Id*. ¶ 205. CAP did not obtain an exemption for M5188. *Id*. ¶ 206.

2. As to Counts 1-3 ("Medicaid Fraud And Recoupment — False Claims Act, 31 U.S.C. §§ 3729(a)(1), (a)(2) and (a)(7)" , 5-6 ("Medicaid Fraud And Recoupment — Common Law Fraud and Payment by Mistake of Fact"), 9-20 "(Controlled Substance Violations")

The Maine Department of Human Services administers the Medicaid program on behalf of the U. S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. CAP Quality Care's Statement of Material Facts ("CAP SMF") (Docket No. 131) ¶ 2; Response to Defendant's Statement of Material Facts ("Plaintiff's Responsive SMF") (Docket No. 140) ¶ 2. On August 28, 2001 Noa Shinderman executed a Medicaid/Maine Health Program Provider/Supplier Agreement ("Provider Agreement") on behalf of CAP Quality Care. *Id*. ¶ 3. The Provider Agreement was, by its terms, "made the date below signed by the Department of Human Services" and by the defendant. *Id*. ¶ 4. Paragraph 37 of the Provider Agreement reads as follows:

> 37. ***Recommendation*** – This Agreement is not valid for any provider/supplier licensed by the Division of Licensing and Certification unless the Division has signed the agreement indicating its agreement.

Id. ¶ 5. The Division of Licensing and Certification never signed the Provider Agreement. *Id*. ¶ 6. The Provider Agreement was never signed by a representative of the Maine Department of Human Services. *Id*. ¶ 7. At the time CAP became a MaineCare provider, the Division of Licensing and Certification did not license methadone clinics. The Government's Additional Facts in Response to the Defendant's Motion for Partial Summary Judgment ("Plaintiff's Additional SMF")(included in Plaintiff's Responsive SMF beginning at 14) ¶ 79; CAP Quality Care's Reply to the Government's Additional Facts, etc. ("CAP Additional Responsive SMF") (Docket No. 153) ¶ 79.[18]

CAP considered itself a Medicaid provider at all relevant times. *Id*. ¶ 58. Between 2001 and 2003, with respect to the vast majority of patients listed by confidential CAP number in column 1 of the government's 29-page spreadsheet of claims (Docket #54, Attachment 1), CAP billed Medicaid (MaineCare) for Procedure Code H0020 for methadone treatment services for each one-week period that started on the corresponding date in column 2 and ended on the corresponding date in column 3, for which Medicaid assigned the corresponding claim number indicated in column 7 and for which Medicaid paid CAP $80 approximately 5 days after the corresponding date indicated in column 8. *Id*. ¶ 61.

Jeff Weiss has been CAP's computer consultant since 2001. *Id*. ¶ 62. One of Weiss's responsibilities was generating the weekly transfer file that was sent to MaineCare that stated the services

[18] The defendant asks the court to strike this paragraph of the plaintiff's additional statement of facts on the ground that it is not a "fact" within the meaning of that term as used in Local Rule 56(b). CAP Additional Responsive SMF ¶ 79. It also objects to the paragraph on the ground that it states a legal conclusion. *Id.* Finally, it contends that the source cited in support of the paragraph "does not provide a basis for a conclusion that [the declarant] is competent to provide admissible evidence regarding the subject matter" of the paragraph. *Id*. The objections are overruled and the requests to strike are denied. The defendant also purports to deny the paragraph., but its denial, a statement of the various forms and (*continued on next page*)

for the patients who paid for their care through MaineCare. *Id.* ¶ 63. In 2001 and 2002, CAP submitted claims to MaineCare electronically and received payment by check together with a report. *Id.* ¶ 68. From 2001 to 2003, if CAP received an overpayment from MaineCare, CAP generally paid the money back. *Id.* ¶ 71.

Since CAP opened for business in October 2001 it has submitted tens of thousands of claims to MaineCare under its MaineCare provider number requesting reimbursement for methadone treatment services. *Id.* ¶¶ 74,[19] 75. In response, MaineCare reimbursed CAP more than $6.8 million. *Id.* ¶ 74.

Marc Shinderman's temporary Maine medical license expired on August 9, 2002. CAP's SMF ¶8; Plaintiff's Responsive SMF ¶ 8. During discovery in this case, the plaintiff disclosed to the defendant a 4-page document entitled "Shinderman Post August 9, 2002 Medical Practice," which lists the date and patient number of documents it maintains demonstrate that Dr. Shinderman was practicing medicine after his temporary Maine medical license lapsed. *Id.* ¶ 9. Eighteen of the documents identified indicate that the relevant patient was either not a Medicaid patient or Medicaid was not billed for the service. *Id.* ¶ 10. Marc Fecteau, Director of the Program Integrity Unit of the Office of MaineCare Services, designated by the plaintiff as an expert witness, submitted a report of his findings dated April 12, 2006. *Id.* ¶ 11. Fecteau stated that with regard to the allegations in the Second Amended Complaint of practicing medicine without a license "Dr. Shinderman's lack of licensure would not necessarily affect the MaineCare Program's reimbursement for services." *Id.* ¶ 14. The defendant has treatment plans for 66 of the 70 patients named in the 4-page document. *Id.* ¶ 15. Dr. Shinderman was not the sole qualified professional who signed and

titles over time of the unit or division of the state department that licensed CAP, *id.*, does not address the substance of paragraph 79 of the plaintiff's additional statement of facts, which accordingly is deemed admitted.

[19] The defendant asks the court to strike this paragraph of the plaintiff's statement of additional facts. CAP Additional Responsive SMF ¶ 74. It contends that the paragraph does not state a "fact" as that word is defined in this court's Local (*continued on next page*)

authorized 63 of the treatment plans after August 9, 2002, meaning that this lack of licensure would not affect MaineCare reimbursement. *Id*. ¶¶ 14, 16. For the three other treatment plans, the signature of the authorizing physician is unclear but the style of dating the signature is that customarily used by Dr. Keefe, not Dr. Shinderman. *Id*. ¶ 17.

With respect to the failure to individualize treatment plans alleged in the Second Amended Complaint, Fecteau stated that the MaineCare Benefits Manual provides in part that an "individualized treatment plan shall be approved, signed, and dated by a physician [or other specified type of health care worker] within thirty (30) days of the date [the] recipient began treatment." *Id*. ¶¶ 18-19. Fecteau stated that he would "generally accept [a] generic treatment plan if[] it occurred with only a minority of the patients, and the provider individualized the plan within the 90-day review period." *Id*. ¶ 20.

Fecteau indicated that he would not take recoupment action with respect to patient M496 since the patient was only seen for 4 weeks. *Id*. ¶ 21. He indicated that he would not take recoupment action with respect to patient M513 since the patient was only seen for 8 weeks and was discharged before the 90-day review was required. *Id*. ¶ 22. He stated that although he considered the treatment plan "generic and not individualized," he would not take recoupment action with respect to patient M538 since the patient was only seen for 8 weeks and was discharged before the 90-day review was required. *Id*. ¶ 24. He indicated that he would not take recoupment action with respect to patient M796 since the patient was only seen for one week and was discharged prior to the 30-day time frame for approving the initial treatment plan. *Id*. ¶¶ 25-26. He indicated that he would not take recoupment action with respect to patient M815 since the patient was only seen for one week and was discharged prior to the 30-day time frame for approving the

Rule 56(b). *Id*. The request is denied.

initial treatment plan. *Id*. ¶ 27. He stated that the treatment plan for patient M888 was generic and not individualized but that he would not take recoupment action since the patient was only seen for one week and was discharged prior to the 30-day time frame for approving the initial treatment plan. *Id*. ¶ 28. He considered the treatment plan for patient M357 generic and not individualized but indicated that he would not take recoupment action since the patient was only seen for two weeks and was discharged prior to the 30-day time frame for approving the initial treatment plan. *Id*. ¶ 29.

CAP has held a valid DEA registration with the number RC0277106 since October 2001 which authorizes it to dispense methadone to its patients. *Id*. ¶¶ 30-31. From October 2001 until September 2003, CAP dispensed methadone to its patients under the authority of this registration. *Id*. ¶ 32. The following chart lists the applicable start and end counts, the difference between the two counts, and the percentage that the difference represents of the total liquid methadone on hand at the defendant's clinic:

Week	Start Count	Previous End Count	Difference	% of Total
18	421,105 ml	421,100 ml	5 ml	0.00118%
20	150,930 ml	151,000 ml	70 ml	0.04637%
21	243,635 ml	243,485 ml	150 ml	0.06156%
55	652,826 ml	652,676 ml	150 ml	0.02297%
63	491,771 ml	491,750 ml	21 ml	0.00427%
82	702,339 ml	702,389 ml	50 ml	0.00711%
85	612,875 ml	613,125 ml	250 ml	0.04079%
105	423,430 ml	423,680 ml	250 ml	0.05904%
108	379,199 ml	379,329 ml	130 ml	0.03428%

Id. ¶ 46. The following chart lists the applicable start and end counts, the difference between the two counts, and the percentage that the difference represents of the total tablet methadone on hand at the clinic:

Week	Start Count	Previous End Count	Difference	% of Total

62	892,925 mg	892,925 mg	0 mg	0.00000%
76	363,755 mg	363,705 mg	50 mg	0.01374%
78	304,060 mg	304,070 mg	10 mg	0.00328%
82	922,030 mg	922,020 mg	10 mg	0.00108%
85	1,147,040 mg	1,147,060 mg	20 mg	0.00174%
90	313,980 mg	313,990 mg	10 mg	0.00318%
97	904,540 mg	904,550 mg	10 mg	0.00110%
98	396,370 mg	396,375 mg	5 mg	0.00126%
105	1,020,275 mg	1,020,675 mg	400 mg	0.03920%
106	529,770 mg	529,850 mg	80 mg	0.01510%
108	379,390 mg	379,600 mg	210 mg	0.05535%
109	753,330 mg	753,340 mg	10 mg	0.00132%

Id. ¶ 50.

On September 9, 2003 a team of investigators searched CAP pursuant to a search warrant. *Id*. ¶ 54. The plaintiff's agents seized a file labeled "Biennial Inventory due 10/3/03." *Id*. ¶ 56. In this case, the alleged DEA record-keeping violations are primarily based on the CAP inventories that were obtained during the September 9 search pursuant to the search warrant. Plaintiff's Additional SMF ¶ 84; CAP Additional Responsive SMF ¶ 84.[20] From September 16, 2001 through January 4, 2004 Steven Maynard was CAP's nurse manager. *Id*. ¶ 82.[21] For several weeks following the search, CAP's attorneys, chief executive officer, clinical director, medical director, pharmacist and chief information officer asked Maynard to explain the inventory variations and appearance of errors in CAP's record-keeping system. *Id*. ¶ 85.[22]

[20] The defendant asks that this paragraph of the plaintiff's additional statement of facts be stricken as legal argument. CAP Additional Responsive SMF ¶ 84. That request is denied. In the alternative, the defendant admits this paragraph. *Id*.

[21] The defendant purports to qualify this paragraph of the plaintiff's additional statement of facts but does not support its qualification with a citation to the summary judgment record. CAP Additional Responsive SMF ¶ 82. Because the paragraph is supported by the citation to the summary judgment record given by the plaintiff, Plaintiff's Additional SMF ¶ 82, it is deemed admitted, Local Rule 56(e).

[22] The defendant asks that this paragraph of the plaintiff's statement of additional facts be stricken "because it is not a statement of a fact, but rather an unsubstantiated assertion that is merely the opinion of the affiant." CAP Additional Responsive SMF ¶ 85. The defendant makes the same request with respect to paragraphs 86 and 87 of the plaintiff's statement of additional facts. *Id*. ¶¶ 86-87. In each case, the request is denied. As to paragraph 85, the defendant also (*continued on next page*)

On about October 30, 2003, Maynard responded with a memorandum explaining his concerns about CAP's record-keeping system, in which he stated, *inter alia*:

i) there were "many areas of the DoPi [23]program that are flawed to such an extent that errors of omission and commission are commonplace;"

(ii) during Maynard's tenure, the software program "has shown repeated and sufficient weakness to place [CAP] in a position of being suspected of diversion of methadone;"

(iii) those system weaknesses "have been mentioned repeatedly and yet [CAP] continued[d] to have daily issues arise that merit a 'bandage' rather than significant improvement;"

(iv) CAP needed to make a "genuinely concerted effort" to repair the problem or "abandon the project of developing this flawed product in favor of a proven dispensing program that may be available on the market."

Id. ¶ 86.[24] In the same memorandum, Maynard confirmed for CAP's senior management the following list of problems that was "certainly not all inclusive:"

(i) one source of the problem was that CAP's record-keeping system was "very dependent on user accuracy" and required staff "to master a convoluted series of manipulations;"

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asserts that it "denies the underlying information as being a matter of opinion, not fact." *Id*. ¶ 85. To the extent that it is possible to understand this "denial," it appears to be essentially an objection to the paragraph, which is overruled.

[23] The Second Amended Complaint states that "[i]n order to keep track of its methadone supply and distribution . . . CAP utilized a computer system known as DoPi." Second Amended Complaint ¶ 413. The plaintiff also refers to DoPi as "a computerized system of records." Plaintiff's Additional SMF ¶ 99. No explanation of the derivation of the name is provided in the summary judgment record.

[24] In addition to the objections already discussed, the defendant contends that this paragraph "violates the provisions of Fed. R. Evid. 407 because it attempts to rely upon evidence of subsequent remedial measures in order to prove negligence, culpable conduct." CAP Additional Responsive SMF ¶ 86. None of the statements reproduced above involves a subsequent remedial measure; they merely point out existing problems. Indeed, given Maynard's title as "the" nurse manager at CAP, Second Declaration of Steven Maynard (part of Attachment 7 to Docket No. 140) ¶ 1, it appears likely that his memorandum is admissible as a statement against interest. Fed. R. Evid. 804(b)(3); *see generally Marquis Theatre Corp. v. Condado Mini Cinema*, 846 F.2d 86, 90 n.3 (1st Cir. 1988). The request to strike on this basis is denied, as is the same objection and request made with respect to paragraph 87.

(ii) CAP's record-keeping system allowed "anyone to approach a 'signed-on' computer and make entries using another employee's identification" such that "any person can step [into] his/her terminal and enter doctors [sic] orders, dose patients, change dosing histories, enter nursing notes, enter lab results, [and] eliminate holds;"

(iii) CAP had failed to develop a modification of a "nurse banks" system it used in Chicago that would comply with Maine law;

(iv) CAP's system allowed for manipulation of inventory, including the ability to manipulate opening and closing inventories, and this allowed for ongoing deviations in the weekly inventory totals; and

(v) CAP's use of "superimposed dose plans" introduced a "significant possibility of medication error" when dosing patients.

Id. ¶ 87.

On about February 5, 2004 and March 2, 2004 Maynard provided the following information during a proffer with federal investigators:

(i) the DoPi system did not work;

(ii) "[f]rom the beginning the math didn't add up and DoPi was never able to keep track of the methadone;"

(iii) "[i]t became so bad that a physical inventory had to be taken by hand;"

(iv) "there were many means of introducing errors to DoPi;"

(v) "[i]f working properly, DoPi should have totaled the methadone via printed reports. Physical inventories had to be maintained each day due to the problems with DoPi and when compared to the printed reports, indicated 'vast, significant' discrepancies more often than not;"

(vi) "[t]he majority of the time, the methadone counts revealed a shortage;"

(vii) "[o]ther problems with DoPi were that the electronic records were never secured. Anyone with access to DoPi could alter information from any period of time. 'There was no control;'"

(viii) CAP employee Jeff Weiss "instructed Maynard to utilize[] fictitious client numbers (0000/0001) to 'correct' shortages by making false entries and inventory manipulations;"

(ix) "DoPi had no means to account for spillage" and Maynard was instructed by Weiss or Shinderman to record spillage incorrectly in client records and under fictitious client numbers;

(x) "[t]he DoPi system was manipulated from the beginning of business at CAP" and "Weiss, Shinderman and Cotreau all knew these manipulations were occurring;"

(xi) the "weekly reconciliation reports" were not part of the DoPi system, but were manually created and, according to Weiss, would be the only report DEA could have;

(xii) "[m]ost of the time Weiss gave directions concerning DoPi and Maynard was told by Shinderman to do whatever Weiss sa[id];"

(xiii) "Cotreau was aware of 'lots and lots' of problems with DoPi" and directed Maynard to contact Weiss for answers;

(xiv) the so-called "Book That Doesn't Exist" was stored in the bottom left hand drawer of Cotreau's desk and contained worksheets that were not an "official record;"

(xv) the "Book That Doesn't Exist" was stored in Cotreau's office because "it was not supposed to be in plain view;"

(xvi) the "Book That Doesn't Exist" was "initiated due to regular discrepancies in the methadone accountability" and "Weiss was fully aware of the book and its purpose;"

(xvii) overages were entered in the "Book That Doesn't Exist" but "shortages were not because they might indicate excessive dosing," and "this is why fictitious patient files were created;"

(xviii) "[t]here were constant attempts to correct the problem with DoPi;"

(xix) "[w]hen Maynard approached Noa[] and Mar[c] Shinderman about the DoPi problems, he was told to talk to Weiss," which he did at least three times every week;

(xx) the "very first 'inventory adjustments' occurred within the first three months of operation;"

(xxi) "[w]ithin the first 30 days of operation Maynard and another nurse, Julia Marston, found inconsistencies with methadone totaling in DoPi;"

(xxii) "[i]nventory manipulations" were made "approximately once per month currently and during the first twelve months of operation approximately three times per month;"

(xxiii) "Maynard had no question that Weiss wanted him to create 'spills' for accounting purposes;" and

(xxiv) "Shinderman stated that he didn't care about diversion on the street and that maybe methadone on the street would provide evidence that methadone in a clinic wasn't so bad."

Id. ¶ 88.

Under applicable regulations, CAP's records were required to be complete and accurate. *Id*.¶89. When there is a theft or a loss that the registrant cannot explain, it should be reported to DEA. *Id*. ¶ 90. CAP did not report to DEA any thefts or significant losses during the relevant period of time. *Id*. ¶ 91. Under the DEA record-keeping regulations, there is no written acceptable variance. *Id*. ¶ 93.

C. Discussion

1. Count 4 ("Distribution Of MethadoneIn Violation Of 42 C.F.R. § 8.12(i)").

The plaintiff contends, Motion for Partial Summary Judgment, etc. ("Plaintiff's SJ Motion") (Docket No. 128) at 1-3, that the defendant violated the following two regulations:

(i) Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
(ii) Regularity of clinic attendance;
(iii) Absence of serious behavioral problems at the clinic;
(iv) Absence of known recent criminal activity, e.g., drug dealing;
(v) Stability of the patient's home environment and social relationships;
(vi) Length of time in comprehensive maintenance treatment;
(vii) Assurance that take-home medication can be safely stored within the patient's home; and
(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.
(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.
(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.
(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be give a maximum 2-week supply of take-home medication.
(vii) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs [opiod treatment programs] must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers . . . .

42 C.F.R. § 8.12(i).

(h) Exemptions. An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA [Substance Abuse and Mental Health Services Administration] exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

42 C.F.R. § 8.11(h).

Also relevant is the following regulation:

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

> (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

21 C.F.R. § 1306.07.[25]

The plaintiff contends that "[w]ith respect to each patient and each instance specified in the Facts, CAP was not in compliance with the regulations for the unsupervised use of controlled substances because CAP provided unsupervised or 'take-home' methadone to patients that did not qualify for the privilege . . . . Moreover, in those instances, CAP failed to obtain a Section 8.11 exemption . . . ." Plaintiff's SJ Motion at 6-7. Count 4 of the Second Amended Complaint alleges that CAP knowingly dispensed methadone in violation of 42 C.F.R. § 8.12(i) and, in so doing, violated 21 U.S.C. §§ 829(a) and 842(a)(1). Second Amended Complaint (Docket No. 37) ¶¶ 377-83. Those statutes provide as follows:

> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

21 U.S.C. § 829(a).

> **(a) Unlawful acts**
> It shall be unlawful for any person —

[25] The plaintiff points out that a different version of 21 C.F.R. § 1306.07 was in effect at the time of the alleged violations, which provided: "(a) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependant person for 'detoxification treatment' or 'maintenance treatment' . . . shall be deemed to be within the meaning of the term 'in the course of his professional practice or research' . . . Provided, That the practitioner is separately registered with the Attorney General as required by section 303(g) of the Act (21 U.S.C. § 823(g)) and then thereafter complies with the regulatory standards imposed relative to treatment qualification, security, records and unsupervised use of drugs pursuant to such Act." Plaintiff's SJ Motion at 9.

> **(1)** who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title . . . .

21 U.S.C. § 842(a)(1). "Part C" is 21 U.S.C. §§ 821-30. The defendant does not contend that it is not subject to the requirements of part C. Also relevant is the statutory definition of "dispense" for purposes of section 829(a).

> The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

21 U.S.C. § 802(10). The plaintiff contends that the "split-dosing" practiced by the defendant constituted the provision of methadone, a controlled substance, by an unlawful order and, "[a]ccordingly, CAP's conduct repeatedly violated Section 829 . . . ." Plaintiff's SJ Motion at 8.

The defendant takes the position that "[t]here is a genuine issue of fact whether a 'split dose' constitutes 'unsupervised' use." Defendant's Opposition to Plaintiff's Motion for Partial Summary Judgment, etc. ("Defendant's SJ Opposition") (Docket No. 142) at 6. It points out that the term "unsupervised" is not defined in the regulations. *Id*. It contends that it was "managing" the split-dose given to the patients at issue because they were required to come to the clinic every day for the first portion of the dose and could be monitored and evaluated before being given the second portion to take away with them. *Id*. It offers the opinion of its expert witness that a split-dose regimen differs from a take-home dose and is not unsupervised. *Id*. at 7-8. It also offers the opinion of "[t]he Maine officials responsible for licensing methadone clinics" (although it cites the opinion of only one such individual) "that 'split doses' are different from 'take homes,' and do not require the same degree of regulatory approval." *Id*. at 8. It also asserts

that "[r]egulators" in Missouri and Florida "both followed the same approach as Maine did in 2001 to 2003." *Id*. at 9.

I begin with the fact that the defendant does not offer any evidence to the effect that state licensing agencies are empowered to apply or enforce the federal regulations at issue here or that the responsible federal officials defer to state agencies in this respect. Accordingly, how any employee of a state licensing agency views or interprets the federal regulations is irrelevant to the question whether the defendant has violated those regulations. I will not consider the defendant's last two arguments further.[26]

Next, it appears that the defendant has mischaracterized a dispute over the proper interpretation of the applicable regulations as one of fact. Construction of statutes and regulations is a matter for the court, not for the opinion testimony of experts, however qualified they might be. *United States v. Sinclair*, 74 F.3d 753, 758 n.1 (7th Cir. 1996) ("Our own cases have determined that Federal Rules of Evidence 702 and 704 prohibit experts from offering opinions about legal issues that will determine the outcome of a case."); *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994) ("It is the responsibility of the court, not testifying witnesses, to define legal terms."). *See generally Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 99 (1st Cir. 1997) (error to allow witness to testify that appointments at issue were in violation of law).

Read in context, 42 C.F.R. § 8.12(i) equates "take-home use" with "unsupervised use." It may not reasonably be read to distinguish between the two terms. That being the case, the defendant's attempt to

[26] The plaintiff has moved to supplement its response to the defendant's statement of additional facts with newly-discovered information relevant to this argument. Motion for Leave to Supplement the Government's Reply to CAP's Additional Facts (Docket No. 157). The defendant does not object to this motion. Defendant's Response to Motion for Leave to Supplement (Docket No. 161) at 1. Because it is advisable that the material included in the plaintiff's motion become part of the record of this case, the motion is **GRANTED**, but for the reasons stated in the text, I have not considered any of that material in preparing this recommended decision.

define "unsupervised" as something other than its "split-dose" regimen for certain patients must fail. This reading of the regulation is buttressed by the statement of the purpose of the regulation: to limit the potential for diversion of methadone to the illicit market. Requiring a patient to visit the clinic once a day to consume half of his daily dose of methadone does nothing to limit the potential for the diversion of the half of the dose which that patient then carries away from the clinic. The clinic may well be "managing" the treatment of the patient with this regimen, but that is not the purpose of the regulation.

That said, it is not possible to determine from the summary judgment record whether for each of the patients at issue the defendant's medical director "considered" the eight-point criteria of 42 C.F.R. § 8.12(i)(2). Without examining each patient's entire individual medical record, it is not possible to determine whether that record documents "[s]uch determinations and the basis for such determinations." 42 C.F.R. § 8.12(i)(3). The plaintiff has provided facts about certain patients with respect to one or more of the criteria, but not all. *E.g.*, Plaintiff's SMF ¶¶ 18-25, 28, 35-37, 39, 44, 46-47, 52, 58-59, 64, 69, 75-76, 85-86, 93-94, 97, 164, 171, 201-03. However, the regulation requires the medical director to consider each of the criteria and does not make any one or more of the criteria determinative of the question whether the patient is "responsible in handling opioid drugs." 42 C.F.R. § 8.12(i)(2) & (3). With one exception,[27] in each case in which the plaintiff includes in its statement of material facts the assertion that the defendant's medical director did not document consideration of the 8-point criteria in the patient's record, the defendant denies the assertion and the denial is properly supported by the affidavit of Kathy M. Alarie. Plaintiff's SMF ¶¶ 89, 99, 104, 109, 115, 120, 130, 135, 140, 145, 150, 155, 160, 166, 173, 178, 183, 192, 197,

[27] The one exception is paragraph 125, where the defendant did not include in its denial the factual allegations based on the Alarie affidavit and a citation to the Alarie affidavit. Defendant's Responsive SMF ¶ 125. During a telephone conference on October 12, 2006 counsel for the defendant confirmed that this was an oversight and counsel for the plaintiff had no objection to the court's consideration of paragraph 125 as if it had been so supported.

205; Defendant's Responsive SMF ¶¶ 89, 99, 104, 109, 115, 120, 130, 135, 140, 145, 150, 155, 160, 166, 173, 178, 183, 192, 197, 205; Affidavit of Kathy M. Alarie (Attachment 3 to Docket No. 144) ¶¶ 16-17. The plaintiff accordingly cannot be entitled to summary judgment on the basis of this alleged failure to comply with the regulation.

The plaintiff also contends that the defendant violated 42 U.S.C. § 8.12(i) by providing split doses to patients who did not qualify under the "time-in-treatment" requirements of section 8.12(i)(3). Plaintiff's SJ Motion at 6-7. This argument is based on the following paragraphs of the plaintiff's statement of material facts: 30, 38, 45, 53, 60, 65, 70, 77, 81, 87, 95, 103, 108, 114, 119, 124, 129, 134, 139, 144, 149, 154, 159, 165, 170, 177, 182, 187, 191, 196, 204. The defendant provides an identical denial to each of these paragraphs: "**DENY**. CAP Quality Care denies that a split dose was treated identically as a take home dose." Defendant's Responsive SMF ¶¶ 30, 38, 45, 53, 60, 65, 70, 77, 81, 87, 95, 103, 108, 114, 119, 124, 129, 134, 139, 144, 149, 154, 159, 165, 170, 177, 182, 187, 191, 196, 204.[28] The defendant's citation to the affidavit of its expert witness in support of each denial makes clear that it is denying that a split dose is the equivalent of a take-home dose for purposes of the applicable regulation, a legal question which I have already decided in favor of the plaintiff. In addition, the denial is not responsive to the factual assertion in each listed paragraph of the plaintiff's statement of material facts and accordingly should be disregarded. In each case, the defendant also admits the factual allegations. It is clear, once the

[28] Several of the defendant's responses also include additional denials based on the assertion that its corporate designee under Fed. R. Civ. P. 30(b)(6), in some but not all of the instances in which the plaintiff cited that deposition, "was equivocal in those particular answers and does not meet the requirements of competency set forth in F.R.E. 602," Defendant's Responsive SMF ¶¶ 38, 53, 77, 81; or based on the assertion that "the citation to Weiss Dep. at 131-32 is unsupported by the record because there is a factual dispute, see Affidavit of Kathie [sic] Alarie at ¶¶ 13, 15," *id.* ¶¶ 103, 108, 119, 154, 182, 187, 191. In each instance, the plaintiff has provided citations to other portions of the summary judgment record that support the factual assertions at issue, so the denial does not controvert the factual assertions themselves, which the defendant has in any event admitted.

defendant's legal argument is rejected, that the provision of split doses to each of these patients did violate the time-in-treatment requirements of 42 C.F.R. § 8.12(i)(3).[29]

That is not the end of the matter, however. The complaint alleges violations of statutes, not just of the regulation. The plaintiff contends that the regulatory violation constitutes a violation of 21 U.S.C. § 829(a), which triggers a number of civil penalties, because the take-home methadone was provided to these patients "without a lawful order." Second Amended Complaint ¶ 381; Plaintiff's SJ Motion at 8. However, even accepting the plaintiff's argument that the defendant's conduct in providing "split-dose" methadone to the patients at issue "does not qualify as 'dispensing' [under 21 U.S.C. § 802(10)] because . . . it was pursuant to an *un*lawful order," Plaintiff's SJ Motion at 8 (emphasis in original), it does not follow that the defendant's "split-dose" regimen necessarily violated section 829(a). If, according to the plaintiff's argument, the "split-dose" methadone was not "dispensed directly by" the defendant "to an ultimate user," then section 829(a) requires that it be dispensed by written prescription. 21 U.S.C. § 829(a). The plaintiff's statement of material facts is silent on the question whether written prescriptions were provided for the patients at issue here. It is not a point on which the evidentiary burden may be satisfied by the drawing of an inference, because drawing such an inference from the summary judgment record would be nothing more than speculation. The defendant has provided no evidence on this point, either, so neither side is entitled to summary judgment on this allegation.

[29] The plaintiff's contention that the defendant also violated 42 C.F.R. § 8.11(h) by failing to obtain an exemption for each of these patients, Plaintiff's SJ Motion at 2-3, also appears to be correct, Plaintiff's SMF ¶¶ 31, 40, 49, 55, 61, 66, 71, 78, 82, 90, 100, 105, 110, 116, 121, 126, 131, 136, 141, 146, 151, 156, 161, 167, 174, 179, 184, 188, 193, 198, 206. I reject the defendant's qualification of each of these paragraphs that "a split dose . . . did not require an application for an exemption." Defendant's Responsive SMF ¶¶ 31, 40, 49, 55, 61, 66, 71, 78, 82, 90, 100, 105, 110, 116, 121, 126, 131, 136, 141, 146, 156, 161, 167, 174, 179, 184, 188, 193, 198, 206.

The plaintiff also asserts that the defendant violated 21 C.F.R. §§ 1301.74(k) and 1306.07(a), Plaintiff's SJ Motion at 8-9, and that argument appears to have merit. However, it does not attempt to tie those violations to either of the statutory violations alleged in the complaint. It is therefore unnecessary to address the parties' concern with the appropriate remedies for the regulatory violations, Defendant's SJ Opposition at 9-11; Reply to Defendant's Opposition to Plaintiff's Motion for Partial Summary Judgment (Docket No. 150) at 3-4, because the plaintiff has not established that it is entitled to summary judgment on the arguments it has made in connection with its motion.

The defendant's motion for summary judgment on Count 4 is based on the argument that the regulations of the Medicaid program, of which it apparently contends the DEA regulations discussed above are a part, do not apply to the defendant because it was not a "provider" under the program due to the state's failure to sign the Provider Agreement. Defendant's Motion for Partial Summary Judgment, etc. ("Defendant's SJ Motion") (Docket No. 132) at 2-6. It cites 42 U.S.C. § 1396a(27) for the proposition that it "must first enter into a 'provider agreement' with [Maine's] designated Medicaid agency" in order to seek Medicaid reimbursement. *Id*. at 3. However, that statutory provision is applicable to the state Medicaid agency, not to providers; it requires state plans for medical assistance to "provide for agreements with every person or institution providing services under the State plan," and requires the agreements to contain certain provisions. 42 U.S.C. § 1396a(27). In order to participate in the Medicaid program, providers are required to file with the federal government an agreement that includes certain provisions. 42 U.S.C. § 1395cc(a). A provider is defined by regulation as "any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency." 42 C.F.R. § 400.203.

The provider agreement signed by the defendant does include the following provision:

> 37. ***Recommendation*** — This Agreement is not valid for any provider/supplier licensed by the Division of Licensing and Certification unless the Division has signed the agreement indicating its agreement.

Defendant's SMF ¶¶ 3, 5; Plaintiff's Responsive SMF ¶¶ 3, 5. Neither the Division of Licensing and Certification nor any other representative of the Maine Department of Human Services ever signed the agreement. *Id*. ¶¶ 6-7. Despite its having submitted claims to and received payment from the Medicaid program for years after signing the agreement, Plaintiff's Additional SMF ¶¶ 61, 68, 76; CAP Responsive Additional SMF ¶¶ 61, 68, 76, the defendant now takes the position that it was never a provider to whom the Medicaid regulations were applicable because the state agency never executed the written agreement.

The plaintiff responds that "CAP waived any such argument by failing to assert it as an affirmative defense." Opposition to Defendant's Motion for Partial Summary Judgment ("Plaintiff's SJ Opposition") (Docket No. 139) at 4. The defendant responds, in a conclusory and unhelpful fashion, that "[t]he affirmative defenses set out in the answer to the Second Amended Complaint fairly incorporate the defendant's arguments" and asserts that "[t]he specifics were not known to the defense until May 2006, long after the pleadings were filed,[30] when state authorities revealed that they never signed the agreement." CAP Quality Care's Reply to the Plaintiff's Response in Opposition to Motion for Partial Summary Judgment ("Defendant's SJ Reply") (Docket No. 149) at 2. I cannot agree that the affirmative defenses pleaded by the defendant, Answer, Affirmative Defenses and Demand for Trial by Jury, etc. (Docket No. 45) at 111-14, may reasonably be read to "fairly incorporate" the argument it now raises. However, I also do not agree with the plaintiff that the argument is appropriately characterized as an affirmative defense. The only authority cited by the plaintiff in support of its waiver argument is *Jewelers Mut. Ins. Co. v. N.*

[30] The defendant's answer to the amended complaint was filed on January 31, 2006. Docket. It has made no attempt to (*continued on next page*)

Barquet, Inc., 410 F.3d 2 (1st Cir. 2005), which it describes as "similar." Plaintiff's SJ Opposition at 4. In that case, the First Circuit stated that any reliance on a specific statutory provision "which is in the nature of a statute of frauds" is an affirmative defense under Fed. R. Civ. P. 8(c). *Jewelers Mut. Ins. Co.*, 410 F.3d at 11. A defense that the regulations cited as the basis of a plaintiff's claim against a defendant do not apply to that defendant because a third party failed to comply with a precondition which the third party imposed on an agreement required by the plaintiff is not sufficiently similar to a statute-of-frauds defense to come within the terms of Fed. R. Civ. P. 8(c). The plaintiff does not suggest that any other defense specifically listed in that rule is sufficiently analogous to the situation at hand to permit the court to conclude that the defendant has waived the defense. While the defendant should have moved to amend its answer when it became aware of this defense, this matter is still sufficiently far from going to trial to prevent the defendant from taking any unfair advantage from its failure to do so.

I find more persuasive the plaintiff's contention that the cited provision of the agreement does not apply to the defendant at all. Plaintiff's SJ Opposition at 4-5. By its terms, the provision applies only to "any provider/supplier licensed by the Division of Licensing and Certification." Defendant's SMF ¶ 5; Plaintiff's Responsive SMF ¶ 5. The plaintiff has provided evidence that "at the time CAP became a MaineCare Provider, the Division of Licensing and Certification did not license methadone clinics. Instead, at that time, the Division of Licensing and Certification was only responsible for licensing hospitals, home health organizations and nursing homes." Plaintiff's Additional SMF ¶ 79. The defendant's objections to this paragraph on the grounds that it "involves multiple statements in one paragraph" and states a legal conclusion, Defendant's Responsive Additional SMF ¶ 79, have already been overruled. The defendant

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amend its affirmative defenses in any substantive manner since then. *See* Answer to Second Amended Complaint (*continued on next page*)

also contends that the authority cited for the paragraph, the declaration of Marc Fecteau, "does not provide a basis for a conclusion that Mr. Fecteau is competent to provide admissible evidence regarding the subject matter of ¶ 8 within the meaning of Fed. R. Evid. 602" and requests that the paragraph be stricken. *Id*. To the contrary, Mr. Fecteau's declaration provides adequate information to establish his competence on this issue. Declaration of Marc Fecteau (Attachment 5 to Docket No. 140) ¶ 1. The request to strike the paragraph is denied. Finally, the defendant purports to deny this paragraph in the following manner:

> CAP was licensed by the Medicaid Managed Care/Licensing Unit, of the Maine Department of Mental Health, Mental Retardation and Substance Abuse Services, which became the Licensing Division of the Maine Department of Behavioral and Developmental Services, and which was ultimately subsumed by the Division of Licensing and Certification of the Maine Department of Health and Human Services.

Defendant's Responsive Additional SMF ¶ 79. The fact that the agency that licensed CAP at the relevant time later was "subsumed" by the Division of Licensing and Certification of the Maine Department of Health and Human Services does not change the fact that at the time the Provider Agreement was executed by the defendant, the Division of Licensing and Certification to which it refers was located in an entirely separate department of state government from the agency that licensed the defendant. Paragraph 79 of the plaintiff's statement of additional facts is deemed admitted. The defendant is not entitled to summary judgment on Count 4 on the basis of its "never-a-provider" argument.

Even if this were not the case, the case law cited by the defendant in support of its argument on this point, Defendant's SJ Motion at 3; Defendant's SJ Reply at 3, is distinguishable. In none of those cases was an entity that had submitted claims under and received payment from the Medicaid program seeking to escape liability under regulations applicable to Medicaid providers. *Minnesota Developmental*

(Docket No. 95).

Achievement Ctr. Ass'n v. Haas-Steffen, 20 F.3d 889, 890 (8th Cir. 1994) (plaintiffs had not entered into provider agreements); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1209 (5th Cir. 1980) (interest on notes given by third party for purchase of stock of provider not recoverable by provider under Medicaid); *Town Court Nursing Ctr., Inc. v. Beal*, 586 F.2d 266, 269 (3d Cir. 1978) (whether facility was certified as skilled nursing facility under Medicare provisions); *Spectrum Health Continuing Care Group v. Anna Marie Bowling Irrevocable Trust*, 336 F.Supp.2d 697, 707 (W.D. Mich. 2004) (balance billing); *State of Michigan, Dep't of Soc. Servs. v. Schweiker*, 563 F. Supp. 797, 798 (W.D.Mich. 1983) (whether state could recover federal financial participation for payments made to facility whose provider agreement had expired).

The defendant makes only this argument in support of its motion for summary judgment on Count 4. That motion should be denied.

2. Counts 1-3 ("False Claims Act"), 5 ("Common Law Fraud"), 6 ("Payment By Mistake Of Fact").

The defendant makes the same argument that it made as to Count 4 with respect to Counts 1-3 and 5-6. Defendant's SJ Motion at 2-6. For the reasons already discussed, it is not entitled to summary judgment on this basis.

3. Claims arising from paragraphs 356-67 (Section caption: "Medical Practice Without A Maine License").

The defendant contends that it is entitled to summary judgment "on any claims that Dr. Shinderman practiced medicine after his license expired," although it does not identify any such claims by count of the second amended complaint. Defendant's SJ Motion at 6-8. It asserts that the plaintiff "has failed to produce any evidence showing that MaineCare was charged for the services provided by Dr. Shinderman . . . or that Dr. Shinderman was the sole qualified professional who signed and authorized the treatment

plans" and that this failure entitles it to summary judgment on claims arising from Paragraphs 356-67 of the second amended complaint. *Id*. at 7-8.

The plaintiff responds that it "will not request a monetary recovery for the conduct alleged in paragraphs 356 to 367 of the Second Amended Complaint." Plaintiff's SJ Opposition at 7. It goes on to assert that this "stipulation" does not require "dismissal" of any count in the second amended complaint "since none is addressed particularly to Shinderman's practice of medicine without a license." *Id*. The defendant is accordingly entitled to summary judgment on any claims arising from paragraphs 356-67.

4. Claims arising from paragraphs 313, 316-18, 322-23 and 325 (regarding individualized patient treatment plans).

The defendant contends that it is entitled to summary judgments on any claims arising from allegations that the defendant failed to prepare treatment plans for patients M357, M496, M513, M538, M796, M815 and M888, as set forth in paragraphs 313, 316-18, 322-23 and 325 of the second amended complaint. Defendant's SJ Motion at 8-11. This is so, it asserts, because these patients were treated for periods of time too short to trigger the regulatory requirement to prepare an individualized treatment plan. *Id*. The plaintiff responds that the defendant treated these seven patients "for less than 8 weeks, [so] there would be no Medicaid recoupment even though CAP's treatment plan was not individualized." Plaintiff's SJ Opposition at 7. It asserts that it "will not request monetary recovery due to the lack of an individualized treatment plan for those seven patients." *Id*. Again, it states that this "stipulation does not call for the dismissal of any Count in the Second Amended Complaint since none is addressed to those specific seven patients." *Id.* The defendant is accordingly entitled to summary judgment on any such claims.

5. Count 9 ("Controlled Substance Violations —Liquid Methadone Inconsistent 'Star' and 'End' Counts").

The defendant contends that it is entitled to summary judgment on Count 9 because "there is no obligation to keep start or end counts [of liquid methadone] and make them consistent." Plaintiff's SJ Motion at 11-12. Specifically, it asserts that "there is no DEA regulation requiring a registrant to maintain a weekly or daily inventory, or requiring that the start count for one week's records match[] the end count for the previous week's records." *Id*. at 12. It cites 21 C.F.R. § 1304.21(a) for the proposition that it was not required to maintain a perpetual inventory. *Id*. at 11-12. Count 9 alleges that the start counts of liquid methadone in the defendant's records for 11 specific weeks failed to match the end counts for the immediately preceding week and that the defendant's failure to reconcile those discrepancies was negligent. Second Amended Complaint ¶¶ 434-43. The plaintiff seeks penalties "pursuant to the DEA record-keeping regulations," which are not otherwise specified. *Id*. ¶ 444.

The plaintiff first asserts that the defendant's motion on this count and others brought under the Controlled Substances Act should be denied because the defendant "cites no legal authority that would justify" its approach of selecting certain discrepancies listed in the second amended complaint "and arguing that, in isolation, each is not sufficiently 'substantial' for the imposition of liability or penalties." Plaintiff's SJ Opposition at 7-8. The plaintiff offers no legal authority to support its contrary position.

The only regulation cited by the parties in connection with their arguments with respect to this count is 21 U.S.C. § 1304.21(a), which provides:

> Every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

21 C.F.R. § 1304.21(a). There is apparently no dispute that the defendant is required to keep records pursuant to 21 C.F.R. § 1304.03.

I do not read Count 9 to allege that the defendant was required to maintain a perpetual inventory. Second Amended Complaint ¶¶ 433-44. Nor do I read Count 9 as alleging that each particular example of a difference between a week-end count of liquid methadone and the subsequent week's starting count was itself necessarily a violation of "the DEA record-keeping regulations." *Id*. The plaintiff disclaims any intent so to allege. Plaintiff's SJ Opposition at 12. The cited regulation merely requires that a complete and accurate record be maintained "on a current basis." A pattern of discrepancies could well be considered to demonstrate a failure to comply with the regulation. Contrary to the defendant's assertion, the plaintiff is not "attempt[ing] to create a requirement that the start and end counts be justified." Defendant's SJ Motion at 12. The plaintiff is charging that, absent some recorded reason for the discrepancies, the discrepancies between the two numbers are evidence of an incomplete and/or inaccurate record. Again, contrary to the defendant's argument, whether the plaintiff can "show that the amounts reflected in the end counts and the start counts were incorrect," *id*., is not determinative on this claim. The counts are the counts recorded by the defendant. They differ in a significant and as yet unexplained way that, standing alone, may provide evidence of failure to comply with the regulation. Nothing more is necessary with respect to this count. The defendant's motion for summary judgment on Count 9 should be denied.

6. Count 10 (*"Controlled Substance Violations—Liquid Methadone Failure to Report Inconsistent 'Start' & 'End' Counts*").

This count alleges that the defendant's failure to report the discrepancies in its liquid methadone count in violation of 21 C.F.R. § 1301.74(c). Second Amended Complaint ¶¶ 446-48. The defendant contends that the regulation only requires it to report "any theft or significant loss of any controlled substance

upon discovery of such theft or loss,"[31] that the DEA has no evidence of any theft from its stocks, and that the discrepancies at issue are not "significant." Defendant's SJ Motion at 12-13. It asserts that nine of the eleven discrepancies listed by the plaintiff "are less than one-tenth of one percent" and "there can be no genuine issue that a discrepancy for these nine weeks fails to qualify as significant." *Id*. at 13. It states that it is "entitled to summary judgment on these nine claims." *Id*.

However, as was the case with Count 9, the second amended complaint does not allege eleven separate violations of the regulation at issue. Rather, it alleges in one paragraph that the defendant never reported the discrepancies in these eleven weeks and seeks "up to eleven (11) penalties" under "the DEA record-keeping regulations." Second Amended Complaint ¶¶ 446, 448. In addition, when a term in a regulation is undefined, as is "significant" in section 1301.74(c), the term must not be applied in a vacuum, where a discrepancy of less than one-tenth of one percent might seem to the casual observer not to be significant, but rather must be applied and construed in light of the circumstances of each case and the purpose of the regulation. In such situations, courts routinely turn to any interpretation issued by the agency that issued the regulation under consideration and, so long as the interpretation is reasonable, defer to that interpretation. *Edmonds v. Chao*, 449 F.3d 51, 57 (1st Cir. 2006). Here, the DEA has issued guidelines interpreting its regulations which state, regarding the use of the word "significant" in this context, as follows:

> Regarding "significant loss," there is no single objective standard that can be established and applied to all registrants to determine whether a loss is "significant." Any unexplained loss or discrepancy should be reviewed within the context of a registrant's business activity and environment. What constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. A manufacturer may experience continuous losses in the manufacturing process due to, for example, atmospheric changes or mixing

[31] "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." 21 C.F.R. § 1301.74(c).

> procedures. Such losses may not be deemed by the registrant to be significant and may be recorded in batch records. Conversely, for registrants other than manufacturers, the repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem that must be reported to DEA, even though the individual quantity of each occurrence is not significant.
>
> Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.

Reports by Registrants of Theft or Significant Loss of Controlled Substances, 70 Fed.Reg. 47,094-01 (Aug. 12, 2005) at *47095. While this commentary to the DEA's amendment of 21 C.F.R. § 1301.74 was published more than eighteen months after the events giving rise to this lawsuit, it nonetheless provides the court with DEA's interpretation of the regulation from the time of its inception. *See id*. at *47094 ("There had been some confusion as to what constitutes a significant loss . . . .").

In addition, the regulation itself now lists factors to be considered in determining whether a discrepancy is "significant," none of which involves comparing the amount of the discrepancy to the total amount of the controlled substance on hand.

> When determining whether a loss is significant, a registrant should consider, among others, the following factors:
>
> (1) The actual quantity of controlled substances lost in relation to the type of business;
> (2) The specific controlled substances lost;
> (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
> (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

> (5) Whether the specific controlled substances are likely candidates for diversion;
> (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

21 C.F.R. § 1301.74(c). These factors were proposed to be added to the regulation on July 8, 2003. *Id.* The liquid methadone inventory discrepancies at issue occurred between November 19, 2001 and September 14, 2003. Second Amended Complaint ¶ 430.

The defendant asserts that "[h]ad the plaintiff sought a single penalty for the entire period . . . then CAP concedes that summary judgment would not be appropriate here. The plaintiff has elected not to follow that course. For example, . . . Count 10 alleges that CAP is liable for . . . eleven[] separate $10,000 fines for failing to report the discrepancies to the DEA." Defendant's SJ Reply at 4. In fact, the plaintiff asks for up to eleven fines. Second Amended Complaint ¶ 448 ("the Court should assess CAP *up to* eleven (11) penalties") (emphasis added). That necessarily includes a single fine. Pleading for a range of remedies may not be used to limit the plaintiff to one requested remedy and then allow the defendant to obtain summary judgment on the basis of the implications of that single remedy.

This court should not hold, as a matter of law, that the discrepancies involved in the defendant's records of liquid methadone are not significant. The defendant is not entitled to summary judgment on Count 10.

7. Count 11 ("Controlled Substance Violations — Liquid Methadone DoPi System Shortages and Overages").

In Count 11, the plaintiff alleges that the defendant's liquid methadone inventory revealed an inconsistency between the amount of methadone apparently dispensed and the amount of methadone recorded as dispensed under the defendant's DoPi system for 92 of 94 weeks, that the defendant never reconciled the missing or extra methadone and that "pursuant to the DEA record-keeping regulations," this alleged negligence should result in the assessment of "up to ninety-two (92) penalties." *Id*. ¶¶ 450, 454-55. The defendant contends that "[t]he DEA regulations do not require CAP to maintain a computerized calculation of the amount dispensed to its patients," nor do they require CAP "to 'reconcile the inconsistencies between CAP's dispensing records and CAP's DoPi system,' as alleged in the Complaint." Defendant's SJ Motion at 14.

The defendant does not identify the regulations to which it refers with respect to this count. The plaintiff's response does not address the counts separately. Plaintiff's SJ Opposition at 7-13. The defendant refers to paragraph 49 of its statement of material facts. Defendant's SJ Motion at 14. In that paragraph, the defendant asserts: "It is customary for there to be some discrepancies in these types of records; the manufacturers fill some of the bottles with more methadone than listed on the label, there are spills, and some liquid is lost in the pipettes. Fisher Affid. (Ex. E) ¶ 9." Defendant's SMF ¶ 49. The statement of material facts cites the affidavit of Louis Fisher, the defendant's designated expert witness, as authority for this assertion, and the citation does support it. Affidavit of Louis Fisher (Exh. E to Docket No. 131) ¶ 9. The plaintiff denies this paragraph, asserting that "[u]nder DEA record-keeping requirements, there is no written acceptable variance, . . . and there are mechanisms for a registrant to account for overfills and spills," citing the deposition of Jo Anne Masar and the affidavit of John Buckley. Plaintiff's Responsive

SMF ¶ 49. The cited paragraph of the Buckley declaration supports the first quoted assertion, albeit in somewhat different language. Declaration of John Buckley (Attachment 1 to Docket No. 140) ¶ 11. The cited pages of the deposition of Jo Anne Masar support all but the assertion that there is a mechanism to account for spills. Deposition of Jo Anne Masar (Exh. D to Docket No. 131) ("Masar Dep.") at 93-94, 163.

The plaintiff's only argument on this count posits a claim that the second amended complaint does not make. The complaint does not allege that the defendant was required to maintain a computerized calculation of the amount of liquid methadone dispensed to its patients. Instead, it alleges that the defendant failed to comply with 21 U.S.C. § 827(a)(3), 21 C.F.R. § 1304.11 and 21 C.F.R. § 1304.21. Second Amended Complaint ¶¶ 404, 407-08, 454-55. The evidence on this count proffered by the defendant is disputed by the plaintiff. Even if it were not, the plaintiff's argument goes to the weight to be given the evidence of discrepancies; the proffered evidence is not dispositive. The statute and regulation cited by the plaintiff may reasonably be construed to require the reconciliation alleged by the second amended complaint to be missing from the defendant's records. Under all of these circumstances, the defendant is not entitled to summary judgment on Count 11.

8. Count 12 ("Controlled Substance Violations — Failure To Report Liquid Methadone DoPi Shortages and Overages").

This count alleges that defendant failed to report the discrepancies in its inventories of liquid methadone discussed in Count 11 to the DEA "pursuant to the DEA record-keeping regulations." *Id*. ¶¶ 457-58. The defendant repeats the argument that the magnitude of the discrepancy between the amount of "missing" or "extra" liquid methadone in forty-eight of the ninety-two weeks at issue and the defendant's total amount on hand at the time was so small that those discrepancies cannot have been "significant" and

therefore no requirement that it report those discrepancies could have applied to those weeks as a matter of law. Defendant's SJ Motion at 14. For the reasons already discussed, the court should not make such a ruling on the basis asserted by the defendant. The motion for summary judgment on portions of this count should be denied.

9. Count 14 ("Controlled Substance Violation —Tablet Methadone Inconsistent 'Start' & 'End' Counts").[32]

In this count, the second amended complaint alleges that the defendant failed to reconcile discrepancies between week-ending and immediately following week-starting counts of methadone tablets for twelve specific weeks, in violation of "DEA record-keeping regulations." Second Amended Complaint ¶¶ 466-71. The defendant repeats its arguments with respect to the similar claims about liquid methadone set forth in its argument with respect to Count 9. Defendant's SJ Motion at 14-15. For the reasons already discussed in connection with Count 9, the motion on this count should be denied as well.

10. Count 15 "(Controlled Substance Violations —Tablet Methadone Failure To Report Inconsistent 'Start' & 'End' Counts").

Like Count 10, Count 15 alleges that the defendant's failure to report the discrepancies involving methadone, this time in tablet form, set forth in Count 14 violated 21 C.F.R. § 1301.74(c). Second Amended Complaint ¶¶ 473-75. The defendant repeats the argument it made with respect to liquid

[32] Under the heading "Controlled Substances Act Issues," the defendant starts its introductory paragraph with the statement "Counts 9 through 20 allege that CAP violated various regulations relating to record-keeping requirements." Defendant's SJ Motion at 11. The plaintiff apparently interprets this statement as an assertion that the defendant seeks summary judgment on all of these counts. Plaintiff's SJ Opposition at 7-13. However, the defendant specifically addresses in its motion only certain counts between Count 9 and Count 20, and the only conclusion to be drawn from this approach is that summary judgment is not sought on those counts not specifically addressed.

methadone. Defendant's SJ Motion at 15-16. For the reasons discussed in connection with Count 10, the motion for summary judgment on this count should also be denied.[33]

11. Count 16 "(Controlled Substance Violations — Tablet Methadone DoPi System Shortages And Overages").

Like Count 11 with respect to liquid methadone, Count 16 alleges that the defendant's failure to reconcile the discrepancies in its tablet methadone records violates "DEA record-keeping regulations." Second Amended Complaint ¶¶ 477-82. The defendant makes the same argument with respect to this count that it made in connection with Count 11, although it concedes that counting tablet methadone is "not as complicated as liquid methadone" for the purpose of maintaining an inventory. Defendant's SJ Motion at 16. For the reasons discussed in connection with Count 11, the defendant is not entitled to summary judgment on Count 16.

12. Count 17 ("Controlled Substance Violations — Tablet Methadone Failure To Report DoPi System Shortages And Overages").

Count 17 repeats the allegations of Count 12, which dealt with liquid methadone, with respect to failure to report to the DEA the missing or extra methadone tablets shown by comparison of its records. Second Amended Complaint ¶¶ 484-85. The defendant makes the same argument in connection with this count that it did with respect to Count 12, including the assertion that it is entitled to summary judgment with

[33] In its reply memorandum, the defendant for the first time contends that it is entitled to summary judgment with respect to Week 62 on this count because "the plaintiff does not contest that the starting count for Week 62 is identical to the end count of the previous week." Defendant's SJ Reply at 5. It is true that the chart included in the defendant's initial motion, Defendant's SJ Motion at 15, and in its statement of material facts, Defendant's SMF ¶ 50, both show identical numbers for the start count and previous end count for week 62. However, the plaintiff's response to that paragraph in the defendant's statement of material facts was a qualification, asserting that "CAP's reference to Week 62 as a week with 0% discrepancy is an erroneous reference to the wrong week; at the deposition of Jo Anne Masar, the undersigned counsel corrected the record and pointed out that the government was alleging a discrepancy in week 62, not week 61." Plaintiff's Responsive SMF ¶ 20. What counsel for the plaintiff said at that deposition was that he was amending the complaint to allege that the discrepancy was between the beginning count of Week 61 and the end count of week 60. Masar Dep. at 230. The defendant's portrayal of the allegation as remaining one involving Week 62 in its motion filed (*continued on next page*)

respect to some of the weeks included in the allegations in Count 17. Defendant's SJ Motion at 16-17. The defendant is not entitled to summary judgment on Count 17 for the reasons set forth in my discussion of Count 12.

four months later is clearly incorrect. In any event, an argument raised for the first time in a reply memorandum will not be considered by this court. *See In re One Bancorp Sec. Litig*., 134 F.R.D. 4, 10 n.5 (D. Me 1991).

13. Count 19 ("Controlled Substance Violations — Inaccurate Biennial Inventory").

This count alleges that CAP is required to make a complete and accurate record of all stocks of methadone on hand every two years (an exercise that is known as a "biennial inventory"), that a folder seized during execution of the search warrant on September 9, 2003 labeled "Biennial Inventory due 10/3/03" included a page with the defendant's biennial inventory dated April 30, 2003 which was inconsistent with the defendant's printout from its DoPi system dated April 30, 2003, that handwritten notes on the April 30, 2003 DoPi printout reflect that the defendant had knowledge of the discrepancy prior to the execution of the search warrant, and that the defendant knew or should have known of the discrepancy before September 9, 2003 but failed to reconcile it, thereby violating DEA record-keeping regulations requiring the maintenance of an accurate biennial inventory. Second Amended Complaint ¶¶ 496-512.

The defendant contends that its biennial inventory "was not due until October 2003" and that it accordingly was "simply not required to have an accurate biennial inventory at the time of the raid." Defendant's SJ Motion at 17. The plaintiff responds that "although CAP may not have been required to take its biennial inventory until October of 2003, CAP's own paperwork indicates that it chose to take its biennial inventory on April 30, 2003, which is the date that CAP signed and dated the inventory." Plaintiff's SJ Opposition at 13.

As the governing statute provides:

> **(1)** [E]very registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply . . . .

21 U.S.C. § 827(a)(1). The applicable regulation makes this even more clear.

> (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

21 C.F.R. § 1304.11(c). If there is confusion about whether the defendant intended the label on its file or the date and title on the document inside the file to be determinative, the summary judgment record reflects that such confusion was created by the defendant. In light of the conflicting dates, the defendant is not entitled to summary judgment on the basis that the biennial inventory was not due until a date after the file was seized, as the defendant appears to have taken such an inventory, as it was entitled to do, some months before the file was seized. This is precisely the sort of issue that must be sorted out by a factfinder.

III. Conclusion

For the foregoing reasons, (i) the defendant's motion to exclude (Docket No. 133) is **DENIED**; (ii) I recommend that the plaintiff's motion for summary judgment on Count 4 be **DENIED**; and (iii) I recommend that the defendant's motion for partial summary judgment be **GRANTED** as to any claims arising from paragraphs 313, 316-18, 322-23, 325 and 356-67 of the Second Amended Complaint and otherwise **DENIED.**

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum and request for oral argument before the district judge, if any is sought, within ten (10) days after being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

Dated this 7th day of December, 2006.

/s/ David M. Cohen
David M. Cohen
United States Magistrate Judge

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